

University of South Wales



2059406

UNIVERSITY OF GLAMORGAN

**“Pharmaceutical lobbying in Argentina: A study of
Pharmacopolitics”**

JAVIER DE RENTERIA

**A THESIS IN PARTIAL FULFILMENT OF THE REQUIREMENTS
OF THE UNIVERSITY OF GLAMORGAN FOR THE DEGREE OF
DOCTOR OF BUSINESS ADMINISTRATION**

SUBMITTED SEPTEMBER 2006

Acknowledgements

I am indebted to the following persons who have offered their expert advice, support and encouragement throughout my candidature. Firstly, I would like to express my gratitude to Professor Dr. Kerry Howell for his support, advice and encouragement as supervisor. I also want to thank Dr. Markus Kuehl for his support during all the stages of the doctorate programme. Special thanks to my wife and my children who have encouraged and motivated me on this scholarly journey. I would also like to thank all the participants in the study.

Table of contents

| | |
|---|-----------|
| Acknowledgements | I |
| Table of contents | II |
| List of figures | V |
| List of Tables | VI |
| List of Appendices | VII |
| Definition of Terms and Abbreviations | VIII |
| Abstract | X |
| CHAPTER 1: INTRODUCTION | I |
| 1.1 Background of the study | 1 |
| 1.2 Profile of author | 5 |
| 1.3 Aim and focus of the research | 8 |
| 1.4 The significance of the study | 11 |
| 1.5 Research Design | 19 |
| 1.6 Overview of the thesis | 22 |
| 1.7 Conclusion | 25 |
| CHAPTER 2: THEORETICAL PERSPECTIVES | 26 |
| 2.1 Introduction | 26 |
| 2.2 Formal macro-theory: Political models and interest group theory | 28 |
| 2.2.1 Pluralism and Corporatism | 28 |
| 2.2.2 Interest Groups theory | 40 |
| 2.3 Formal meso-theory of lobbying: lobbying models | 47 |
| 2.3.1 Introduction | 47 |
| 2.3.2 Different models of the theory of lobbying | 47 |
| 2.3.3 Reduced form lobbying models | 47 |
| 2.3.4 Contribution payments to an incumbent government | 49 |
| 2.3.5 Transmission of information | 55 |
| 2.3.6 Lobbying model with a mixed approach | 61 |
| 2.4 Formal micro-theory: Pharmapolitics, pharmaceutical industry's influence on politicians and managed care settings | 63 |
| 2.4.1 Introduction | 63 |
| 2.4.2 Lobbying of Congress and Public Officials in the USA | 67 |

| | | |
|--|---|------------|
| 2.4.3 | Lobbying of Managed care organisations | 80 |
| 2.5 | Conclusions | 88 |
| CHAPTER 3: METHODOLOGY: GROUNDED THEORY | | 94 |
| 3.1 | Methodology | 94 |
| 3.2 | Issues of methodological choice | 94 |
| 3.2.1 | Modernism and Post-Modernism | 94 |
| 3.2.2 | Paradigms of Inquiry | 97 |
| 3.2.3 | Methodologies for research | 103 |
| 3.2.4 | Ontological, epistemological, and methodological assumptions related to inquiry paradigms | 108 |
| 3.3 | The research questions | 110 |
| 3.4 | The research domain | 110 |
| 3.5 | Deciding on research methodology | 111 |
| 3.5.1 | Grounded Theory: Glaser or Strauss? | 112 |
| 3.6 | Theoretical Sensitivity | 114 |
| 3.7 | Coding | 114 |
| 3.7.1 | Open Coding | 114 |
| 3.7.2 | Axial Coding | 115 |
| 3.7.3 | Selective Coding | 116 |
| 3.7.4 | Coding for process | 116 |
| 3.8 | The conditional matrix | 118 |
| 3.9 | Theoretical Sampling | 120 |
| 3.10 | Substantive and Formal Theory: Identifying Issues | 121 |
| 3.11 | Conclusion | 122 |
| CHAPTER 4: DATA COLLECTION AND ANALYSIS | | 124 |
| 4.1 | Introduction | 124 |
| 4.2 | Description of the research site and context for the research | 124 |
| 4.3 | Data Gathering Strategies | 127 |
| 4.3.1 | Researcher bias | 128 |
| 4.3.2 | Ethical considerations | 130 |
| 4.3.3 | Interviews | 131 |
| 4.3.4 | Participant Observation | 140 |
| 4.3.5 | Analysis of relevant documents | 142 |
| 4.4 | Data Analysis | 142 |

| | | |
|---|---|------------|
| 4.4.1 | Initial Analysis | 143 |
| 4.4.2 | Re-categorising the data | 149 |
| 4.5 | Conclusion | 152 |
| CHAPTER 5: DEVELOPING SUBSTANTIVE THEORY | | 154 |
| 5.1 | Introduction | 154 |
| 5.2 | Interview questions and interviewee time table | 154 |
| 5.3 | The interview results | 157 |
| 5.4 | From the data to the categories | 211 |
| 5.5 | Core category | 213 |
| 5.6 | Substantive Theory | 214 |
| 5.7 | Conclusion | 217 |
| CHAPTER 6: CONCLUSIONS | | 219 |
| 6.1 | Introduction | 219 |
| 6.2 | Discussion of the substantive theory with the formal theory | 220 |
| 6.2.1 | Substantive theory and formal macro-theory of lobbying | 220 |
| 6.2.2 | Substantive theory and formal meso- theory of lobbying | 228 |
| 6.2.3 | Substantive theory and formal micro-theory of lobbying | 237 |
| 6.2.4 | Summary | 241 |
| 6.3 | Conceptual findings | 243 |
| 6.3.1 | Position of the pharmaceutical industry in the corporatism-pluralism scenario | 243 |
| 6.3.2 | Pharmaceutical lobbying style | 245 |
| 6.3.3 | Pharmaceutical lobbying process model | 248 |
| 6.3.4 | Cooperative and individual lobbying | 253 |
| 6.4 | Limitations of the Research | 255 |
| 6.5 | Reflexivity considerations | 256 |
| 6.6 | Future research | 258 |
| 6.7 | Reflections on my intellectual journey | 259 |
| 6.8 | Contribution to knowledge | 261 |
| 6.9 | Conclusion | 262 |
| References | | 264 |

List of figures

| | |
|--|------------|
| <i>Figure 1 Time – Structural Conditions.....</i> | <i>117</i> |
| <i>Figure 2 Fixed Set of questions.....</i> | <i>137</i> |
| <i>Figure 3 Second set of sub- categories.....</i> | <i>148</i> |
| <i>Figure 4 Model of transfer of decision making power.....</i> | <i>162</i> |
| <i>Figure 5 Building Trust Model</i> | <i>190</i> |
| <i>Figure 6 Lobbying process model.....</i> | <i>191</i> |
| <i>Figure 7 First stage negotiation process:.....</i> | <i>197</i> |
| <i>Figure 8 Second stage Negotiation process.....</i> | <i>204</i> |
| <i>Figure 9 Pharmaceutical industry in the pluralism-corporatism Axis.....</i> | <i>244</i> |
| <i>Figure 10 Lobbying style model.....</i> | <i>246</i> |
| <i>Figure 11 Pharmaceutical lobbying model</i> | <i>249</i> |
| <i>Figure 12 Corporate and individual lobbying strategy.....</i> | <i>254</i> |

List of Tables

| | |
|--|------------|
| <i>Table 1 Research Process</i> | <i>21</i> |
| <i>Table 2 Trends in US and EU lobbying</i> | <i>44</i> |
| <i>Table 3 Comparison of Health Care Systems (adapted from Vincent 2003)</i> | <i>64</i> |
| <i>Table 4 Modernism/ Postmodernism and Paradigms</i> | <i>98</i> |
| <i>Table 5 Guba & Lincoln Basic beliefs of Alternative Inquiry Paradigms(2001)</i> | <i>102</i> |
| <i>Table 6 Researcher's approach to the research object.....</i> | <i>109</i> |
| <i>Table 7 Pharmacopolitics breakdown by company</i> | <i>125</i> |
| <i>Table 8 Breakdown by time in the job.....</i> | <i>126</i> |
| <i>Table 9 Breakdown by type of interviewee.....</i> | <i>133</i> |
| <i>Table 10 Breakdown by years of experience.....</i> | <i>135</i> |
| <i>Table 11 Breakdown by Academic Qualification.....</i> | <i>135</i> |
| <i>Table 12 Integration of the categories</i> | <i>150</i> |
| <i>Table 13 Interview timetable and coding.....</i> | <i>155</i> |
| <i>Table 14 Motivations concepts.....</i> | <i>164</i> |
| <i>Table 15 Participants in the lobbying process.....</i> | <i>173</i> |
| <i>Table 16 Negotiation profile matrix.....</i> | <i>199</i> |
| <i>Table 17 Sub-Categories</i> | <i>212</i> |

List of Appendices

- Appendix 1 Axial and open coding tables
- Appendix 2 Participant information sheet and consent form
- Appendix 3 Stage One Papers

Definition of Terms and Abbreviations

The following definitions will clarify the terminology and its use in this thesis.

- **HMO:** Health Maintenance Organisations offer prepaid, comprehensive health coverage for both hospital and physician services.
- **PBM:** Pharmacy Benefits Management are third party organisations that administer prescription drug benefits.
- **Pharmacopolitics:** Lobbying activities carried out by the pharmaceutical industry aimed at influencing government, the public and HMO officials.
- **Pharmacopolitics manager:** The in-house lobbyist of a pharmaceutical company.
- **Formularies:** An HMO approved list of prescription drugs available to individuals dependent on their health care coverage and only through specific pharmacies. HMOs often restrict or limit the type and number of medicines allowed for reimbursement by limiting the drug formulary list. Formularies are either "closed," including only certain drugs or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs.
- **Rebates:** Reimbursements given to HMOs and PBMs related to the consumption of a pharmaceutical company's products on a specific formulary. This reimbursement is given in return for the inclusion of the company's products in a closed formulary.

- **Dossier:** Information given to the HMOs and public officials about a new product or technology. The dossier could include scientific evidence, approval of the product, clinical trials and pharma-economic studies.
- **Generic drug:** A generic drug is the chemical equivalent of a drug that has an expired patent. When a brand name drug's patent expires, other pharmaceutical companies can produce the same active chemical compound and sell the drug under its generic name.

Abstract

The main purpose of the research was to examine the process of lobbying in the context of the pharmaceutical industry. It sought to explore “why” and “how” multinational companies carried out pharmaceutical lobbying in Argentina.

The study aimed to build valid substantive theory that could be used to analyse pharmaceutical lobbying from different perspectives and used corporatism and pluralism to explain the relationship between the pharmaceutical industry and government. The application of interest groups formation theory permitted the identification of the pharmaceutical industry as an interest group and the identification of its lobbying style. Lobbying theories based on contribution payments and transmission of information were explored in order to understand the use of these policies in the process of pharmaceutical lobbying. The review of literature on American pharmaceutical lobbying helped in understanding the peculiar instruments and practices present in pharmaceutical lobbying and gave the reader an understanding of the characteristics of this market.

The research took a phenomenological methodological approach and the research paradigm was post-positivist and constructivist. The researcher followed the grounded theory methodology approach of Strauss and Corbin. The researcher collected data through in-depth semi-structured interviews and participant observation of in-house and external pharmaceutical lobbyists as well as officials.

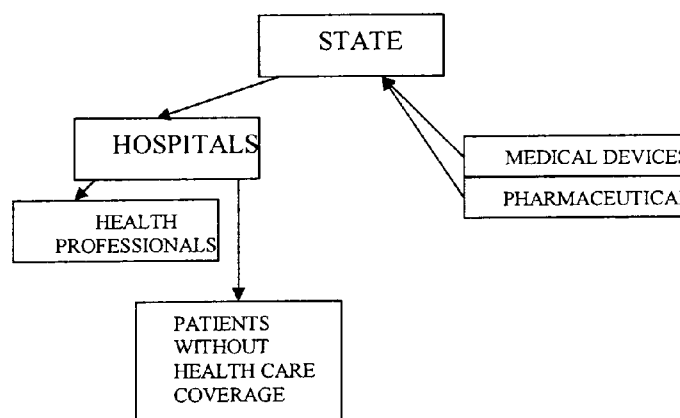
The study made several contributions. Firstly, it positioned the pharmaceutical industry as an interest group in the pluralism-corporatism axis as a means to provide a framework for the understanding of its lobbying activities. Secondly, the study defined the lobbying style of the pharmaceutical industry in Argentina compared to lobbying

performed in the USA and the EU. Thirdly, it provided a pharmaceutical industry basic lobbying model for Argentina that can be tested in other countries. Finally, it provided a model of cooperative or individual lobbying that stated when it was convenient to build coalitions.

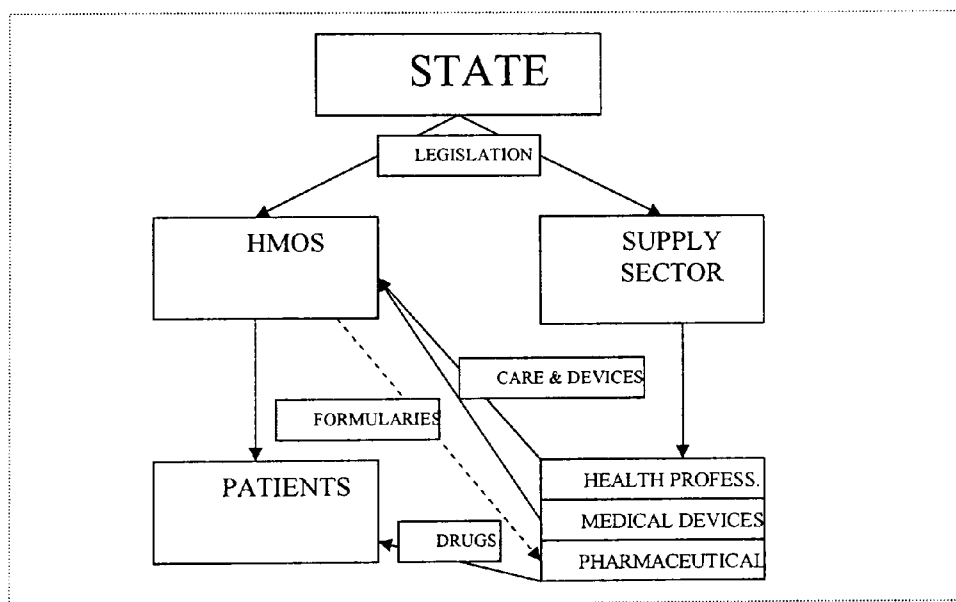
CHAPTER 1: INTRODUCTION

1.1 Background of the study

Health care is one of the most important issues for a government in terms of economic resources, votes and the quality of life for a country's inhabitants (Neri, 2002). Health care in Argentina was regulated by the state and provided by Health Management Organisations (state, provincial, trade union and private) as well as by public hospitals and was supplied by health professionals, the pharmaceutical industry and the medical devices industry. This third sector - the supply sector - consistently maintained an interest in influencing both the regulation and provision sectors with the aim of obtaining a larger share of the market. For the purposes of illustration the researcher created two simplified schemas that depict the supply-demand dynamics of the Argentine system. Firstly, the researcher showed the provision of health care by state hospitals to people without health care coverage. This part of the population mainly represents those on a low-income or without a formal job. The following figure depicts the "public health care system" dynamics:



The state, through tenders and via its national and provincial administrative departments, bought the medicines and medical devices to supply to state hospitals. Health professionals were contracted by the hospitals to provide health care to patients without health care coverage; the hospitals should provide medicines and health care. The reality was that most of the time, due to the lack of funds, out-patients received no medicines and surgery patients had to buy medical devices such as pace-makers, prothesis, etc. This is the supply-demand dynamics of the public system. However, this research focused on the private system that consisted of the state as a regulator, the Health Management Organisations (HMOs) as the providers of health care, the pharmaceutical industry, the health professionals and the medical devices industry as the supplier to the HMOs. The following schema depicts the dynamics of the private health system:



The state, through congress and its administrative departments, enacted legislation and regulations that influence the business and profits of the HMOs and the supply sector. Health maintenance organisations offered prepaid, comprehensive health coverage for

both hospital and physician services. They contracted clinics and individual physicians to provide health care to their affiliates. They also contracted pharmacies to ensure that their affiliates received a reimbursement when they bought medicine. The supply sector was composed of health professionals, the medical devices industry and the pharmaceutical industry. The health professionals and clinics were contracted by the HMOs to provide health care to its affiliates. The medical devices industry sold its medical devices to the HMOs, such as stents, prothesis, pace-makers, etc. The pharmaceutical industry sold medicine directly to the pharmacies. Patients bought them from the pharmacies and received reimbursement. The connection between the pharmaceutical industry and the HMOs began with the introduction of closed formularies. A formulary was an HMO approved list of prescription drugs available to individuals dependent on their health care coverage and only through specific pharmacies. HMOs often restricted or limited the type and number of medicines allowed for reimbursement by limiting the drug formulary list. Formularies were either "closed," including only certain drugs or "open," including all drugs. The objective of the pharmaceutical companies was to have their products included in the closed formularies. The two schemas are a brief description of how the supply-demand dynamics of the system worked. The system has been explained further in following chapters.

Changes in federal legislation had a dramatic impact on the strategy and performance of companies within the health care industry. As health care was one of the most sensitive issues for voters, and for legislators, any law passed by parliament received a lot of attention from the media and the public. During the past few decades legislators had both economic and social motives for their increased commitment in health affairs. Legislators had selected specific areas of the health industry, and specific companies,

for monitoring standards, subsidies, protection, regulation and deregulation. The importance of the legislative process to health businesses was highlighted by congressional debates over issues such as medicines, HMOs and medical care (Vazquez, 2002).

In response to an active congressional agenda, interest groups- such as the trade unions, professional associations and the pharmaceutical industry- employed a wide variety of means to attempt to influence the legislative process. These tactics included financial contributions to the legislators or their parties and direct lobbying of legislators through professional lobbyists or corporate executives (Felicio, 2002).

In recent years the multinational pharmaceutical industry significantly increased its investment in lobbying. Felicio (2002) mentioned two important changes in health care regulations that persuaded the multinational pharmaceutical companies to create a full-time job of in-house lobbyist. The first was the issue of the “Programa Medico Obligatorio” (PMO) law, which passed through Parliament with little influence from the pharmaceutical industry. This law dictated which pharmaceutical drugs and medical practices must be reimbursed by the HMOs.

The second was the introduction of closed formularies in the HMOs. A closed formulary was a restricted list of products; only products on the list would be reimbursed. These lists were made available to physicians and pharmacists in order to guide them in the prescribing and dispensing of pharmaceutical products (Dranove 2003). The objective behind the introduction of formularies was cost containment. Formularies, and their implications, are explained in Chapter Two.

Corporate executives realised that they needed to devote new resources towards lobbying HMOs and legislators. Consequently, departments were created within the

companies where managers not only devoted their attention to lobbying the legislators but to lobbying all the key players in the health care system such as HMOs and central and provincial governments. This type of lobbying activity carried out by the pharmaceutical industry in Argentina has been named "*pharmacopolitics*" and the managers in charge of the activities are *pharmacopolitics managers*.

The role of the *pharmacopolitics manager* essentially involved "lobbying the key officials in the health care system so as to introduce new policies or changes to existing regulations, which would benefit the pharmaceutical companies" (Quiñones 2002). The main objective of this position was to lobby legislators and both public and HMO officials. According to Moloney (1996), *pharmacopolitics managers* were in house lobbyists who lobbied only for their employer. The characteristics of the job are described in chapters Two and Four. Vazquez (2002) suggested that *pharmacopolitics* activities were a highly effective means, perhaps the single most effective means, by which multinational pharmaceutical companies might influence the federal legislative process and the HMOs.

1.2 Profile of author

I hold a Masters Degree in Business Administration from the Argentine Catholic University (UCA) and an Accountancy Degree, also from UCA. I taught Costs at UCA after I finished my degree and held the position of head of assistant professors. My vocational background, after I finished with the University, was in marketing and sales. For many years, I worked in a marketing and sales role for multinational companies including Novartis, GSK, Altana, Roche, Schering and Pfizer. I started working as a *pharmacopolitics manager* for Alcon Labs Argentina, a multinational pharmaceutical company dedicated to the field of ophthalmology, in June 2001. I began as a

counsellor/advisor in pharmacopolitics and one year later was appointed pharmacopolitics manager. My responsibilities were to lobby HMO and public officials mainly with the aim of securing formulary positions for the company's strategic products. This was the first time I had worked full-time as an in-house lobbyist having previously carried out occasional lobbying in the marketing and sales jobs. As mentioned before, I began my DBA in February 2002 and so my learning curve in the pharmacopolitics job grew in parallel with the development of my research. It was a parallel process of reflection in the research project and the understanding of the lobbying process in my job; complete understanding was never final but always in a process of development, through introspection and interaction with others in the lobbying process.

During this process I, the researcher, also had to decide on the ideal methodology for the research. The researcher initially had the idea to develop a quantitative Bayesian approach but gradually changed to an approach that tallied with the game theory as the meso-theory of lobbying was mostly based on the game theory. However, the researcher realised that this was taking an analytic approach to understand a few controlled variables and a systemic approach was required for a deeper understanding of the interaction of variables in a complex environment. Consequently, the approach decided on was phenomenological with the ultimate aim of developing a deep understanding of the lobbying process carried out by multinationals in Argentina. The researcher analysed the different possible methodologies available and concluded that *case study research* and *grounded theory* were the best fit for the research process. The researcher first opted for a *case study research* methodology looking for literal and theoretical replication across the cases. However, later, the researcher decided to use *grounded theory* as a methodology due to the distinctive advantage that it commenced from

specific 'grounded in reality' situations (a pharmaceutical company) with the intent of understanding the nature and rationale of observed incidents. The literature review was carried out at the same time as the change of methodology. The researcher followed the DBA process by going from practice into theory and back to practice. He began with an empirical knowledge of the research subject, reviewed the formal theory and through the process of data collection and building sub-categories so developed the substantive theory. At the same time as the research process developed, the researcher became a member of the pharmacopolitics committee of the Multinational Pharmaceutical Chamber (CAEMe), of the pharmacopolitics committee of Disprofarma and of the audit committee of HMO agreements of the multinational companies in Argentina. This provided the opportunity of experiencing new situations in which cooperative lobbying decisions were made, i.e. when lobbying was carried out by coalition.

The main issue for the researcher was how to detach himself from previously held beliefs and to diminish bias in the research process. The researcher was concerned not with the interviews themselves but in the interpretation of concepts that were implied in the interviews. It was useful to be an 'insider' as, most of the time, the language used was indicative of situations or events already known to the researcher. The fact of being a participant of the research subject provided access and understanding of the processes studied but on the other hand posed the problem of bias in the interpretation of the data. It was an important tool for the researcher to be able to identify the effect of 'self' in the relationship between actions and interactions, as this could affect the research subject and the development of the substantive theory. In the study the researcher tried to maintain theoretical sensitivity and checked the data gathered by a process of constant comparative analysis. In this way the researcher remained focused on the data and the development of the substantive theory of pharmaceutical lobbying rather than self

analysis or allowing the research to be derailed by preconceived ideas. The researcher tried to avoid bias through the iterative and constant comparison of the data.

1.3 Aim and focus of the research

This study focused on the multinational pharmaceutical industry and addressed the question of how pharmaceutical companies influenced both the government and Health Management Organisations (HMOs). For the purpose of this research these two types of activities are referred to as *pharmacopolitics* (Quiñones, 2002) as defined in Argentina. The research also looked at the expected outcomes and motivations of pharmacopolitics activities. The study developed substantive theory concerning how, in Argentina, government officials were lobbied and HMOs influenced, especially in the design of formularies. The study only concerned itself with the multinational pharmaceutical industry in Argentina.

The researcher first considered investigation lobbying from the perspective of the individual company as a lobbying actor. Through the research process it became apparent that it was also necessary to consider the pharmaceutical industry as an interest group that also lobbied officials and the government and pursued special interests for the whole industry or groups of companies. Therefore, the research describes companies and their pharmacopolitics managers as lobbying actors and the pharmaceutical industry, or coalitions of companies, as an interest group. In order to accomplish the aims of this study, the following research questions were asked:

- a) Why do multinational pharmaceutical companies in Argentina lobby officials?
- b) How do multinational pharmaceutical companies carry out lobbying activities?

The question “why” reflected the incentives of pharmaceutical companies to influence legislators and the decisions of officials. The question “how” reflected how the lobbying process was undertaken by pharmaceutical companies. The researcher used the two main research questions, together with the literature review, for the development of a fixed set of sub-questions for the interview process. The interviews were the main origin of this study’s data, followed by participant observation, therefore the researcher needed to develop a broad set of interview questions to be able to gather as much as data as possible to build the substantive theory. The fixed set of questions are as follows:

- a) Who are the officials that pharmaceutical companies choose as targets for lobbying?*
- b) What do you think are the key motivations for pharmaceutical companies to lobby public and HMO officials?*
- c) What are the objectives that you seek when you lobby officials?*
- d) Who are the participants in the process of pharmaceutical lobbying?*
- e) What do you think are the key issues for success when you engage in lobbying?*
- f) How would you describe the process of pharmaceutical lobbying?*
- g) Which strategy do you follow if you want to influence an official?*
- h) How much relevance do you give to scientific information in the process of lobbying?*
- i) Are there other non-scientific instruments that you use to achieve your objective?*
- j) When a lobbying process is not successful, what do you do next?*
- k) Is pharmaceutical lobbying carried out alone or in a cooperative way?*
- l) Do you think that it is possible to free-ride?*

The answers to these questions were therefore the origin of the majority of the data in this research. The researcher modified the approach to these questions to adapt to the different perspectives of the interviewee i.e. whether they were a pharmacopolitics manager, a public or HMO official or an external lobbyist. The questions helped to ensure the same information resulted from the interviews and facilitated the process of coding and building the categories. The questions were open and aimed at enhancing the richness of the data; they also permitted the researcher to probe each of the responses in depth. The interviews generated the most important data for this research. The approach to the research questions has been explained in detail in the methodology chapter.

The researcher's objective was not to focus on the moral implications of lobbying. The researcher aimed to develop substantive theory about the pharmaceutical lobbying process separate from moral considerations. The term 'contribution payments' was found in the meso-theory of lobbying. Grossman and Helpmann (1994) were first to state that contributions provide incentives for the politician to deviate from the best policy choice and that payments were given to political parties. The different authors who extended Grossman and Helpmann's model (including Grossman and Helpmann (1995)) used the term devoid of any moral implications- not mentioning whether the contribution payments were for the officials themselves or the political parties- and left the moral interpretation of the models to the reader. The researcher followed the neutrality shown in the meso-theory of lobbying but at the same time recognised that contribution payments as a term, within the research, was ambiguous- sometimes it depicted corruption in the process of lobbying. The culture in which the research took place, the Argentine market, also permitted a wide acceptance of contribution payments. 'Ethics' emerged as a concept in the open coding process and the researcher comments briefly on this concept in Chapter Five.

1.4 The significance of the study

Pharmaceutical lobbying as a subject has been studied from the perspective of its application in different markets, especially in the USA. There have been numerous reports from interest groups such as Public Citizen (2001) and Common Cause (2001), that have explained the implementation of pharmaceutical lobbying in Washington. The researcher, on beginning the literature search for pharmaceutical lobbying in Argentina, found that there had been no systematic review of how the lobbying process was undertaken by pharmaceutical companies in this country. Thus, the focus of this proposed doctoral research - lobbying by the multinational pharmaceutical industry in Argentina - was new and had not been studied before. The researcher found an opportunity to build theory about pharmaceutical lobbying in Argentina, contribute to the body of knowledge concerning lobbying theory and also provide a basis for investigators to test the theory in other countries.

The researcher first focused on finding a definition of lobbying that would give a common framework for the research process. Lobbying was an instrument available to those interested in advocating and advancing their interests and objectives openly with respect to legislative and executive decision making (Jobst, 2002) but as a term was used in different contexts and situations with different interpretations. The Oxford English Dictionary Online (2002) defined lobbying as:

“1. To influence (members of the house of legislature) in the exercise of their legislative functions by frequenting the lobby. Also, to procure the passing of (a measure) through congress by means of such influence”

“2. To frequent the lobby of a legislative assembly for the purpose of influencing members’ votes; to solicit the votes of members”

The Merriam-Webster Dictionary (2002) introduced “influencing public officials” to the definition and therefore broadening the target of lobbying and not limiting it only to the legislators. It also defined lobbying as an influence “toward a desired action”. It confirmed that there was an objective to be reached. Eisenhardt & Bourgeois III (1988) used a broad definition of lobbying in which the target of lobbying could be any official. Moloney and Jordan (1996) broadened this definition stating that lobbying included an intelligence role (monitoring, interpretation, research) and an operational role (planning and representation to decision makers). Moloney and Jordan’s (1996) approach was used for this research as it provides a framework to understand the word lobbying every time it is used.

The researcher secondly analysed lobbying regulations in different countries to determine whether different regulations could affect the research process. Lobbying in the USA *per se* constitutes a lawful opportunity available for interest groups to exert influence and to impact on policy. Interest groups and lobbying actors had to disclose their investment on lobbying congress, which provided transparency to the system (Public Citizen, 2004). The right to lobby in the USA (Jobst, 2002, p.3) was derived implicitly from the First Amendment of the Constitution which stated “Congress shall make no law [...] abridging the freedom of speech or of the press; or the right of the people peaceably to assemble and to petition the Government for redress of grievances”. The rationale of lobbyists stems from the belief that a democratic society did not necessarily guarantee equal access of individual opinion and, hence, any tool to foster awareness of the legislators about certain topics should be allowed. As Lord (2000, p.293.) wrote, legislators “face a lack of knowledge about relevant public policy priorities and preferences” due to limited personal and staff time and resources. Lord (2000) also confirmed that legislators must rely to a great degree on the information that

they received from different lobbying groups in order to make decisions on different subjects. In the European Union there was an increase in lobbying following the Single European Act (Howell, 2004). Mazey and Richardson (1993) commented that officials in the European Community were trying to accommodate to lobbying exerted by pressure groups because there was no regulation of the activity. In Brussels there was debate about how to establish greater transparency in lobbying but, at the time of writing, there had been no regulation except for voluntary initiatives (Meliss, 2006). The researcher discovered that lobbying in Argentina was not regulated (Neri, 2002). In 2003, President Kirchner issued a decree whereby public officials should divulge interviews with companies, external lobbyists or interest groups where the official could be requested to make a decision regarding a particular interest. Public officials, with the exception of one minister, did not comply with the decree (Rosales, 2006). So, essentially, lobbying in Argentina was not regulated. This lack of regulation helped the interviewees to freely express their opinions about how lobbying was executed by the pharmaceutical industry in Argentina.

The researcher reviewed the literature in order to identify the theoretical perspectives around which to carry out the research. The researcher approached the formal theory of lobbying from three different perspectives. The macro-theory of lobbying referred to the different models about interest group formation. The study of the theoretical models of pluralism and corporatism, with its variations of meso-corporatism and corporate pluralism, provided the basis for understanding how interest groups were incorporated as co-responsible partners in the decision-making process. The research addressed the position of the pharmaceutical industry as an interest group in the pluralism-corporatism axis. Salisbury's (1984) definition of interest group indicated that corporations, state and local governments, universities, think tanks and other institutions of the private

sector were also groups with interest representation. The researcher used this definition of interest group when he referred to the pharmaceutical industry. Interest group theory (Olson, 1965, Salisbury, 1969) shifted attention from external to internal interest group problems, focusing on why members adhered to an interest group. Olson (1965) in his *Logic of Collective Action* stated that a rational, self interested individual would not contribute to the costs of collective action and thus would free-ride unless there was coercion to force them to do otherwise. Furthermore he stated that there had to be selective incentives to group members so that they stayed in the group. Walker (1991), Maloney & Jordan (1997), Kimber (1981) disagreed with Olson and provided new insights to the theory. The researcher investigated free riding and coercion among companies. Salisbury (1969) emphasised the role of the “entrepreneurs” within the interest group. Walker (1983) introduced the concept of *patronage*, which stated that there were some groups that were funded by the government or private interests. The author studied interest group theory in relation to lobbying- the subject area of this research. Olson (1965) and Moe (1980) saw lobbying as a by-product of group activity. Salisbury (1969) suggested that lobbying by group leaders was related to the leaders’ choice and values and not to members’ demands. Salisbury (1984) identified corporations as important lobbying actors. Moloney and Jordan (1996) also noted the interaction of corporations in government decision circles. Howell (2004) and Kirchner (1980) referred to organisations that influenced the public bodies by lobbying for the interests of the sector that they represented. Woll (2006) and Coen (1997) noticed that the term interest groups excluded firms and their political influence yet firms were important lobbying actors. For this research the pharmaceutical industry is considered an interest group and the pharmaceutical companies and pharmacopolitics managers as lobbying actors. The researcher studied the lobbying activity of the pharmaceutical industry as an interest group and researched group formation between pharmaceutical

companies and the relationship between members of a coalition. The researcher also investigated the lobbying activities of the individual company as actors in direct representation of their interests in decision-making circles. Woll (2006) argued that lobbying style was different depending on the context in which lobbying actors carried out their lobbying. The researcher identified and compared the pharmaceutical lobbying styles of the USA and the EU to those in Argentina.

After analysing interest group theory, the researcher decided to focus on the meso-theory of lobbying. One of the research questions was how lobbying was exerted and the meso-theory of lobbying proved to be the most appropriate for this purpose. The meso-theory of lobbying was based on game theory and Nash's equilibrium. It provided a logical framework of how lobbying was exerted. The meso-theory of lobbying considered two channels of influence: contribution payments and transmission of information, the first being contribution payments. Grossman and Helpman (1994) developed the first model by adapting the common agency theory to the lobbying situation. This model established an official and a set of interest groups. The interest groups made offers to the official to try to influence his/her decision. The official had to decide which action to take and how this decision reduced aggregate welfare. Rama and Tabellini (1998) established the cooperation between interest groups in the model. Grossman and Helpman (1995) completed the model with the interaction of lobbying actors in different countries. Maggi and Rodriguez Clare (2000) introduced the choice of different policy instruments. Damania and Fredriksson (2000) focused on the incentives to free-ride when different interest groups followed a common interest. The other channel of influence was the transmission of information. The motive for this lobbying policy was that officials had incentives to listen to interest groups when they were imperfectly informed and interest groups possessed better information about the

relevant policy (Neske, 1997). This related strongly to the concept of "bounded rationality" developed by Simon (1955). Officials faced uncertainty about the future policies and they could not incur costs in acquiring information. These two factors limited the extent to which officials could make a fully rational decision. Simon (1955) claimed, they had only "bounded rationality", so that they could only make decisions based on their previous beliefs and with the information they received from interest groups. Officials were forced to make decisions not by "maximisation"- which meant the best rational decision based on perfect information- but by "satisficing", based on imperfect information provided by the interest groups. The basic communication models were developed by Potters and van Winden (1992) and Ainsworth (1993). In these models the interest groups provided information to the official. The interest group guided the official in his/her policy by providing information. The official had to decide whether or not to trust the information received by the interest groups. Austen-Smith and Wright (1992) introduced counteractive lobbying by two interest groups. Lohmann (1993) added a model with multiple interest groups and the official had to decide which information to accept according to his/her preferred policy decision. Lagerlof (1997) introduced the concept that the interest group was imperfectly informed and that it had to acquire costly information if the official expected it. Lohmann (1995a) and Austen-Smith (1998) developed models regarding access buying where the interest groups made contributions in order to transmit the information. Most of authors wrote about one channel of influence or the other. The only model, that the researcher found, with a mixed approach was developed by Bennedsen and Feldmann (2001) where they assumed that an interest group might influence an official's decision in two independent ways. Firstly, the interest group acquired costly information and provided it to the official or secondly the interest group might engage in contribution payments to compensate the official for a deviation of the preferred policy. This model integrated the

two channels of influence found in the meso-theory. The formal meso-theory of lobbying helped the researcher to identify how lobbying was performed by the pharmaceutical industry or by individual companies through its pharmacopolitics managers. The discussion of the meso-theory and the substantive theory permitted the researcher to develop a conceptual model of the pharmaceutical lobbying process, which is described in Chapter Six.

The formal micro-theory of lobbying described the application of lobbying in the pharmaceutical context. As mentioned previously, there was no relevant literature regarding pharmaceutical lobbying in Argentina so that the researcher decided to review the American literature. Vasallo (2002) mentioned that the American health system was the most similar to the Argentine one. Vincent (2003) compared the European and American health systems and also concluded that the American was the most similar to the Argentine. There was also a philosophical similarity in that health care in Argentina, as in the USA, is a private good that can be accessed by those who can pay for it. In Europe, by contrast, healthcare is a public good and the whole population is allowed some degree of health care for nothing. The American literature depicts how pharmaceutical lobbying exerted influence on congress and showed how the pharmaceutical industry implemented its lobbying strategy. The micro-theory have also included a description of the peculiar instruments and practices that were present in pharmaceutical lobbying so the reader has an understanding of the characteristics of the pharmaceutical market. Some of these instruments and practices are also present in the relationship between the British NHS and NICE, as an evaluation agency, and the pharmaceutical industry. Herxheimer (2003) stated that *patronage* of patients' organisations by pharmaceutical companies for lobbying NICE was commonly used. Quenell (2001) mentioned that pharmaceutical companies carried out lobbying of NICE

and she also stated that a decision by NICE, regarding interferon, was overruled due to direct lobbying by the pharmaceutical industry of the Department of Health (Quenell, 2003). Adams (2004) described that the Association of British Pharmaceutical Industry (ABPI) carried out cooperative lobbying regarding a price regulation scheme on behalf of its members. Corporate Watch (2003) stated that ABPI lobbied the Government to support the pharmaceutical and biotech industries on issues such as taxes, advertising to the public, parallel imports and drug prices. Rogers (2003) mentioned that the UK pharmaceutical industry contributed funding for NHS services and resources that would otherwise not be available, for example equipment or nurses' salaries. This issue was not common practice in the USA or Argentina.

As mentioned above, there had been no systematic review of how the lobbying process was undertaken by pharmaceutical companies in Argentina. The research findings from this study added to an existing body of knowledge of pharmaceutical lobbying relating to research in other countries. The findings contributed to the general knowledge of lobbying and provide a deeper understanding of how pharmaceutical lobbying was carried out in Argentina. The study made several contributions. Firstly, it positioned the pharmaceutical industry as an interest group in the pluralism-corporatism axis as a means to provide a framework for the understanding of its lobbying activities. Secondly, the study defined the lobbying style of the pharmaceutical industry in Argentina compared to that performed in the USA and the EU. Thirdly, it provided a pharmaceutical-industry lobbying-model for Argentina that can be tested in other countries. Finally, it provided a model of cooperative or individual lobbying that stated when it was convenient to build coalitions. The models and substantive theory developed in this research could be tested in other industries within Argentina or in the same industry in other countries. This study recognised, from the perspective of the

pharmaceutical industry, that lobbying occupied an important role within companies and that resources were allocated and continue to be allocated for this purpose.

1.5 Research Design

Data analysis followed the methodology of grounded theory based on the Strauss & Corbin (1998) model. The data was coded (open, process, axial, selective) in order to develop concepts, sub-categories and the core category and thus establish connections between the core category and its sub-categories which permitted the building of a theoretical framework. Sub-categories were integrated in a core category- **pharmaceutical lobbying**. The researcher compared the substantive theory to the formal theory in order to improve the construct definitions.

Four analytic (and not strictly sequential) phases of grounded theory building were identified: research design, data collection, data analysis and literature comparison. The researcher followed seven procedures or steps within these phases:

- a) Review of the literature: This focused on the subject to be researched supporting the definition of the research questions.
- b) Selecting cases: The researcher aimed at theoretical sampling and selected those cases that could maximise the opportunities for comparative analysis until achieving saturation of the categories.
- c) Development of rigorous data collection protocol: The protocol permitted the creation of a database for the data gathered from interviews, participant observations and archival data. The protocol strengthened grounding of theory by triangulation of data from different sources.

- d) Field work: During the interviews there was an overlap of data collection and analysis which speeded analysis and revealed helpful adjustments to data collection procedures.
- e) Analysis of data: The substantive theory was built using open coding, axial coding, coding for process and selective coding.
- f) Saturation of sub-categories: process ended when marginal improvement was small.
- g) Comparison of substantive theory with formal theory: This comparison helped to improve the emergent theory and the researcher could establish the domain to which the study's findings were analytically generalised. The researcher could corroborate or refute the existing theory based on the research findings.

The researcher evaluated these phases and steps against three research quality criteria (Yin, 1994): construct validity, internal validity and external validity. Reliability was not evaluated as the main research criteria was validity.

Construct validity was enhanced by establishing clearly specified operational procedures in the data-gathering phase and coding. Interviews were recorded, a consent form given to interviewees and a set of fixed questions were used. Transcription took place immediately after the interviews and explanations written when interpretative work was needed. Notes were taken as a participant observer and written in a diary during the research process. Coding followed the steps of *grounded theory* enumerated by Strauss and Corbin (1998).

By establishing causal relationships whereby certain conditions were shown to lead to other conditions, as distinguished from spurious relationships, it was possible to

enhance internal validity. In this sense, internal validity addressed the credibility or "truth value" of the study's findings.

External validity required clearly establishing the domain to which the study's findings could be generalised. Here reference was made to analytic and not statistical generalisation and required generalising a particular set of findings to some broader theory and not a broader population.

Table 1 provides an overview of the phases, steps and tests that were taken. The initial table developed by the researcher began as a normative or prescriptive account of recommended activities and changed to a descriptive account of how these prescriptions were applied in the research. The research process table shows the activities that the researcher implemented to carry out the study. A more in-depth explanation of methodology and the research process is covered in the Methodology Chapter.

Table 1 *Research Process*

| RESEARCH PROCESS | | | |
|------------------------------|---|---|---|
| PHASE | | ACTIVITY | RATIONALE |
| RESEARCH DESIGN PHASE | | | |
| Step 1 | Review of lobbying literature | Definition of research questions | Focus on the subject to be researched |
| Step 2 | Selecting cases | Theoretical sampling | Focused efforts on theoretically useful cases aimed at saturation |
| DATA COLLECTION PHASE | | | |
| Step 3 | Develop rigorous data collection protocol | Create first case database Employ multiple data collection methods | Facilitated construct validity Strengthened grounding of theory by triangulation of evidence. Enhances internal validity |

| | | | |
|------------------------------------|--|---|--|
| Step 4 | Field work | Overlap data collection and analysis | Speeded analysis and revealed helpful adjustments to data collection |
| DATA ANALYSIS PHASE | | | |
| Step 5 | Analysis of data | Use open coding /coding for process Use axial coding Use selective coding | Developed concepts, sub-concepts, processes, and properties Developed connections between concepts and sub-categories Integrated sub-categories into the core category to build a theoretical framework All forms of coding enhance internal validity |
| Step 6 | Saturation of sub-categories | Theoretical saturation when possible | Ended process when marginal improvement becomes small |
| LITERATURE COMPARISON PHASE | | | |
| Step 7 | Compare substantive theory with formal | Comparisons with conflicting theory Comparisons with similar theory | Improved construct definitions, and therefore internal validity Also improved external validity by establishing the domain to which the study's findings can be analytically generalised |

1.6 Overview of the thesis

Chapter One presents the background to the research topic, namely pharmaceutical lobbying in Argentina. The profile of the author was described as well as his role as a practitioner in the research project. The researcher explained the aim and focus of the study. The objectives of the research were explicit, namely addressing the research

questions of why and how the pharmaceutical industry carried out its lobbying process. The researcher noticed that there was no literature regarding pharmaceutical lobbying in Argentina so that the study aimed to fill a knowledge gap and make a contribution to lobbying theory. The researcher described briefly the theoretical perspectives and enumerated the contributions to knowledge of the research. The researcher also presented the research design and depicts the various phases and steps undertaken.

Chapter Two explores the current literature in the field of lobbying and deals with the theoretical perspectives of lobbying and its political context. The formal macro-theory of lobbying is discussed in part one. The different models of the political system in which interest groups were formed, mainly pluralism and corporatism, and how interest groups were incorporated within the process of decision-making have been described. The first section also provides an insight into interest group theory. Section two is dedicated to the formal meso-theory of lobbying. It explains the definition and the theory of lobbying based on the game theory. It describes the different models available and analysed two different approaches: contribution payments and transmission of information models. Section three explains the formal micro-theory of lobbying, that was the application of pharmaceutical lobbying in the USA. There was no literature on pharmaceutical lobbying in Argentina so the researcher chose the USA as it had the biggest pharmaceutical market (Quiñones, 2002) in the world and secondly because it was the most similar to the Argentine market (Vasallo, 2002). The reason for considering the micro-theory of lobbying was to illustrate the peculiar instruments and practices that were present in pharmaceutical lobbying so that the reader had an understanding of the characteristics of this market. Section four discusses the issues of methodological choice and defines the researcher's position in the modernism and post-modernism movements and the paradigms of inquiry. It also describes the different

methodologies that the researcher considered for this study and reviews the different phenomenological approaches to research. The researcher chose grounded theory methodology based on Strauss & Corbin (1998) model for this study.

Chapter Three outlines the aim and focus of the research and the research questions and sub-questions. This chapter describes the inductive–deductive stance of the researcher and the methodology choice, namely grounded theory. It identifies the reasons why a grounded theory approach was chosen and its application to the research area and the process of formulating the substantive theory. This chapter deals with the theoretical sensitivity and the reflexivity of the researcher in the study. The conditional matrix shows the relationship between the macro and micro conditions in the research process facilitating the analysis. The coding and theoretical sampling are briefly commented on.

Chapter Four portrays the research context, namely the job of pharmapolitics in multinational pharmaceutical companies in Argentina. It depicts the data collection strategies and the methods used in order to formulate the documentary evidence for the research. Details about the sampling and the criteria used are also documented. The researcher explains the data analysis process and how the concepts, sub-categories and core category were formed.

Chapter Five presents the substantive theory that arose from the process of open coding, coding for process, axial coding and selective coding. The seven sub-categories- Target, Motivations, Participants, Product, Building trust, Strategy and Cooperative lobbying - are explained and the core category identified: *pharmaceutical lobbying*. Quotations from respondents illustrate the findings. The substantive theory that emerged from the data is explained.

Chapter Six compares the substantive theory with the formal theory of lobbying and demonstrates both the similarities and differences. This comparison provides the basis from which to develop four different models: the position of the pharmaceutical industry in the pluralism-corporatism scenario, the pharmaceutical lobbying style model, the pharmaceutical lobbying process and the cooperative and individual lobbying strategy. The first two models were based on the formal macro-theory of lobbying and the second two on the formal meso-theory of lobbying. The researcher also points out the limitations of the research and suggested an agenda for future research.

1.7 Conclusion

The main features of the research - the aim, focus of the study and the questions – have been presented. The researcher has also outlined the significance of the study and its contribution to knowledge. The research design and the steps followed by the researcher have been explained. The overview of the thesis provided in this chapter was intended to give the reader a glimpse of the whole document. The next chapter deals with the theoretical perspectives of lobbying. It also explores the different methodologies considered by the researcher and defines the researcher's position in the modernism and post-modernism movements and the paradigms of inquiry.

CHAPTER 2: THEORETICAL PERSPECTIVES

2.1 Introduction

This chapter discusses the formal theory of lobbying and the research methodologies considered by the researcher. Diesing (1972, p.31) stated that “A formal theory is composed of a model plus an indefinite number of interpretations and there is a sharp distinction between model and interpretation. A model is not affected by any of its interpretations, but can be understood and studied in abstraction from all of them”. Howell (2000) stated that substantive theory should be verified against a formal theory and if changes to formal theory are to be made, there must be references to empiricism. The researcher investigated the lobbying literature from three different levels: macro, meso and micro-theory. Formal macro-theory approached the different group formation theories such as pluralism, corporatism and its variations. The importance of these theories was that they contained the basis on which interest groups were formed and show the different motivations for interest group formation. The theory of interest groups was important as those groups were the participants in the lobbying process.

The formal meso-theory considered the theory of lobbying based on academic mathematical models, mainly the game theory. The meso-theory of lobbying provided a logical framework with clear definitions that enabled the researcher to identify the different stages in the lobbying process. One of the research questions was how pharmaceutical companies in Argentina carried out lobbying and, thus, the theory of lobbying based on the game theory provided the foundation to understand how the lobbying process was carried out.

The formal micro-theory of lobbying explained the application of pharmaceutical

lobbying in the USA. There was no literature on pharmaceutical lobbying in Argentina so the researcher chose the USA for two reasons; it was the biggest pharmaceutical market in the world (Quiñones, 2002) and secondly because it was the most similar to the Argentine market (Vasallo, 2002). This research considered the micro-theory of lobbying in order to illustrate the peculiar instruments and practices that were present in pharmaceutical lobbying and to give the reader an understanding of the characteristics of this market.

The research methodologies for this study were also explored. The researcher described the methodologies available in qualitative research, described briefly phenomenology (as a methodology), action research, ethnography, case study and grounded theory and outlined the main characteristics of each. The researcher declared his position on the ontological, epistemological and methodological assumptions related to inquiry paradigms and identifies why grounded theory was the most appropriate methodology for this research.

2.2 Formal macro-theory: Political models and interest group theory

2.2.1 Pluralism and Corporatism

Study of the theoretical models of pluralism and corporatism, with the variations of meso-corporatism and corporative pluralism, provided the basis for understanding how interest groups were incorporated within the process of authoritative decision-making as co-responsible partners in governance societal guidance (Schmitter, 1981). Jordan and Richardson (1987) confirmed that interest or pressure group writings stemmed from empirical studies of the policy process. Johnson (2005) defined the pressure group as an interest group that existed primarily for exerting political influence as a means of affecting government policies or legislation but he remarked that the distinction between the two terms had become less significant in ordinary language. Kavanagh and Jones (1991, p. 224) stated “Interest or pressure groups are formed by people to protect or advance a shared interest” making no distinction between both terms. For the purpose of this study, the researcher will use the terms interchangeable. The researcher explored next the different models of pluralism and corporatism based on how they approached group formation.

2.2.1:1 Pluralism

Although Latham (1952) and Connolly (1969) looked for the roots of pluralism in classical literature, the theory of pluralism was born in the '50s and '60s with Dahl (1956). The pluralist image of a complex political process with multiple participants and uncertain outcomes was itself a denial of elite Marxist corporatist theories. Grant (1989) defined pluralism as the most influential and resilient account of the role of interest groups in a democratic society. Its resilience was due to the variety of positions held by

the different authors. Dahl (1956) argued that power was not dominated by a minority but was spread throughout society with no particular sectional interest being predominant and with each power source being balanced by a countervailing force. Coakley and Gallagher (1999, p 273.) stated that the pluralist model “Maintains that individual interest groups apply pressure on political elites in a competitive manner and attribute power in policy making to individual groups operating in particular areas at particular times”. Dahl (1956) presented this definition of pluralism in his early work but this definition lacked internal coherence as different groups have unequal resources. The proof of this was that Dahl (1984) separated himself from this notion of pluralism in modern political analysis and defended the notion of polyarchy: that is a set of interest groups with unequal resources to influence government or officials. For Dahl (1991), polyarchy was the term that defined pluralist society and American democracy; there were certain groups who could exert more influence on state decision making than others. This influence was dispersed because not all interest groups had the same power in the decision-making process (Dahl, 1991). Jordan (1993, p.51) listed the inequalities found in Dahl’s polyarchy concept:

- 1) Different kinds of resources for influencing officials were available to different citizens and groups.

- 1) Resources were unequally distributed so that certain groups had more resources to influence officials.

- 2) Groups that had access to one resource often had limited access to other resources.

- 3) No one resource dominated in all, or even in most, key decisions.

4) A resource was effective in some issues, or in some specific decisions, but not in all.

5) No group was lacking some influence resources.

The essence of Dahl's (1991) pluralism was that the group resources for influencing were dispersed and that they were not equal. Dahl's theory also abstracted the figure of the state in interest group competition and placed the state as a neutral observer, which was not necessarily the case; he validated, nevertheless, group struggling (Dahl, 1984) related to the state as the means of influencing government actions; interest groups competed for access to the government in order to influence state decisions. Another incongruence in Dahl's perspective was that he recognised that all groups had the ability to influence irrespective of their resources. He did not recognise that certain groups had *de facto* a better position to influence government and that there were others with no influence (Jordan, 1993). Moloney (1996) confirmed this issue stating that the pluralist perspective offered no powerful explanation for asymmetrical distribution of power between groups.

Truman (1951) was the other major figure in the development of pluralism. Although he did not identify himself as a pluralist he could be considered a 'subconscious' pluralist (Jordan, 1993). Truman (1951) validated the existence of interest groups and he considered them a form of democratic expression. Truman (1951) called attention to the many types of resources available to interest groups in gaining the access needed to exercise influence (Browne, 1990). Within those groups, organised business groups competed with each other to obtain a better standing in governing circles (Moloney, 1996). Truman (1951) did not believe in the equality of groups because any system tended to discriminate in favour of established groups and interests and new groups

were denied access to points of decision. Wilson (1973), and Tilly (1978) also confirmed this inequality of interest representation. Truman (1951) also declared that when an interest appeared in the political system a potential interest group would form and occupy this position. This potential group statement could not be verified in reality therefore converting it into an issue of faith for Truman (Jordan & Richardson, 1987). Truman's additional contribution was perhaps his proposition that the overlap of interests held by interest groups mediated and moderated conflict (Jordan 1993). Truman (1951, p.520) said "Overlapping membership among organised interest groups and among these and potential groups is, as we have seen, the principal balancing force in the politics of a multigroup society such as the United States". Interest groups compromised because of the conflicting interests of their members. The validity of this assertion could be only true in a small community as the members of the interest groups were connected; in large national interest groups the leaders did not necessarily have overlapping membership and interests in common with other groups.

Polsby (1971, p. 118) viewed pluralism as "A society fractured into congeries of hundreds of small special interest groups, with incompletely overlapping memberships, widely differing power bases and a multitude of techniques for exercising influence on decisions salient to them". Polsby's pluralism was a methodology to discover who ruled in a community (Jordan, 1993). He recognised that certain groups would be more powerful or govern in certain communities but adhered to Dahl's proposition that no group dominated in all issues. Polsby's (1971) approach did not make a prior assumption that a certain interest group dominated but he could not rule out one group dominating and that not all interest groups had the power to influence (Jordan, 1993). Cox (1988) defined pluralism as a concept in which the question of which groups dominated was an open empirical one. The problem with Polsby, as with Dahl, was that

they tried to differentiate themselves from the concept that given unequal resources there would be unequal influence on government by different interest groups (Browne, 1990).

Lindblom (1965) differentiated himself from the previous writers and introduced the figure of the state as a participant in the competition between interests groups. Dahl's pluralism suffered from being a society-centred theory that failed to give sufficient weight to the state as an actor in its own right. For Lindblom (1965), government was often a major participant. Bentley (1967) defined government as a differentiated, representative group performing specified governing functions for the underlying groups of the population. Lindblom also noticed that the interaction between groups was not always beneficial and that inefficiency and irrationality lay in the competition between interest groups (Jordan, 1993). For Moloney (1996) business groups needed government involvement. Lindblom opposed Dahl (1961), who thought that dispersing power was always beneficial and that "those representing various private parties will in fact rationally mobilize their resources" (Browne, 1990, p.478). Another issue introduced by Lindblom & Braybrooke (1963) was the theory of incrementalism, which stated that there were multiple participants, each with some distinctive position and some political resources. In this theory, the players learnt from experience and increased their power in a certain sector or area. Nevertheless, the approach of Lindblom (1965) confirmed the inequality described by the previous authors: where there was no pure pluralism but a situation where certain interest groups or individuals had a dominant position in decision-making policies. Lindblom (1977) differentiated between interest groups and business in a polyarchy and stated that business had a privileged relationship with government. Business took a number of major decisions off the agenda of the government - for example jobs, prices, production, growth and

standard of living - and as such had a role similar to the public official. Government needed business for the welfare of society and adapted public policy to the needs of business (Lindblom, 1977). Grant (2002) mentioned that New Labour declared itself a pro-business party and had a consultative relationship with business. Lindblom (1977) stated that this situation of inequality between interest and business groups was called neo-pluralism. Neo-pluralists recognised the structural constraints upon the participation of certain groups and the inequality between interest groups, especially when it came to economic issues (Lindblom, 1977). However, the neo-pluralists maintained that there was still a degree of plurality in other policy areas.

Dahl & Lindblom (1976) expressed their views about bargaining between interest groups. They did not like the effect of national bargaining, namely giving power to national organisations instead of the government. This bargaining, along with being heard (Dahl, 1956), fitted in with the pluralist perspective of lobbying executed by dispersed groups with unequal resources.

Jordan (1993) argued that pluralism was an anti-theory more than a theory. He referred to pluralism as a conceptual framework whose importance lay in what it rejected more than what it established. Bachrach & Baratz (1962) and Schattschneider (1960) criticised pluralism on the basis that government and bureaucracy were interested in interaction with interest groups and they were not neutral but an active participant. They rejected the image of government as a neutral arena in which interest groups fairly competed and policies neutrally emerged. They also noted that there were insider groups and outsider groups, the latter being excluded from influencing the decision process. Grant (1989) confirmed this when stating that insider groups were regarded as legitimate by government and were consulted on a regular basis; outsider groups either did not seek to be consulted by government on a regular basis or could not gain

recognition. Jordan (1993) pointed out that the pluralist theory was a collection of different author's views and that there had been no systematic development of the theory.

Nevertheless pluralism was the starting point of the interest group theory. Although some authors included in pluralism the work of Olson (1965) and Salisbury (1969), the researcher included these in the interest groups theory.

2.2.1:2 Corporatism

Historically the use of the term corporatism had a strong normative and ideological component. It was adopted by fascist and communist ideologies, showing an institutional relationship between systems of authoritative decision-making and interest representation. The term became synonymous with the structures of a strong and dominant state (Molina & Rhodes, 2002). Shonfield (1965) observed that, in order to attain a high level of macroeconomic performance within the Keynesian framework, modern economies had promoted processes, including state planning, in which the major interest groups were brought together and encouraged to conclude a series of bargains about their future behaviour. This had the effect of moving economic events along a desired plan. The plan indicated the general direction in which the interest groups, including the state in its various guises, agreed they wanted to go. The work of Schmitter (1974) marked an academic milestone in this conceptual evolution. He clearly defined neo-corporatism as a form of interest representation distinct from pluralism, statism and syndicalism (Molina & Rhodes, 2002). Though Schmitter (1974) saw similarities between the models, he sought to present a clear alternative to pluralism (Jordan, 1993). In the pluralist model, he suggested, there were a large number of competing groups but in a corporatist system there were few groups each in a specially

privileged relationship with the state. Corporatism, according to Schmitter (1979, p.13), could be defined as “A system of interest representation in which the constituent units are organised into a limited number of singular, compulsory, non-competitive, hierarchically ordered and functionally differentiated categories, recognised or licensed by the state and granted a deliberate representational monopoly within their respective categories in exchange for observing certain controls on their selection of leaders and articulation of demands and supports”. The state was at the apex of the corporatist system and organised a hierarchy within which interests operated regarding both the government and other interests.

At around the same time, Lehmbruch (1977, 1979) put greater emphasis on neo-corporatism as a form of policy-making in which concerted action assumed central importance. Lehmbruch (1977) saw corporatism as an institutional pattern of policy formation in which large interest organisations cooperated with each other and public authorities not only in the articulation and intermediation of interests but also in the authoritative allocation of values and the implementation of policies.

The difference between Schmitter (1974) and Lehmbruch (1977) was that the former saw corporatism as a structure of interest representation and the latter saw it as a system of policy making. Despite these differences the common concern of both was in understanding the continuous and structured participation of interest organisations in policy-making and other stages of the policy process, especially policy implementation. Cawson (1985, p.38.) introduced a revised definition which tried to amalgamate both points of view- “Corporatism is a specific socio-political process in which organisations representing monopolistic functional interests engage in political exchange with state agencies over public policy outputs which involves these organisations in a role that combines interest representation and policy implementation through delegated self

enforcement". In short, Cawson (1985) brought together the views of Schmitter (corporatism 1) and the views of Lehmbruch (corporatism 2).

Lehmbruch (1982) accepted strong institutional links between government and organisations, such as having between them regular consultations and group representations in advisory bodies. In addition, Schmitter reviewed his initial definition of corporatism and considered that for "definitional purposes it may be preferable to define concepts in terms of polar opposites... but the real world is located somewhere in between" (Schmitter, 1982, p.265.).

Crouch (1983) located the difference between pluralism and corporatism in the nature of the actors involved and in their internal organisation, rather than in their role in the policy machinery. Insider groups were incorporated in corporatism so that favoured groups played a structured and significant role in policymaking. Martin (1983) argued that the distinction between pluralism and corporatism was the extent to which organised groups were integrated in the policy-making arena of the state. Interest groups operated as integral parts of, rather than external influences on, government activity. This issue, which was essential to the corporatism theory, was downplayed in the pluralist literature.

Lehmbruch (1982) defined corporatism as a pluri-dimensional concept and applied it to different forms of arrangement. Most prominent was the tripartite arrangement between government, unions and business (the iron triangle). But corporatism has been established in many more policy fields (e.g. health) and on different levels as local corporatism (Molina & Rhodes, 2002). The common characteristic was that interest groups acted as equal partners of the state. It was a specific structure of exchange in which interest groups not only represented the interest of their members towards the

state but also the state's interest towards their members. Thus corporatism was not one-way-route but a transaction structure designed to act out commonly defined policies effectively (Wessels, 1997). Competition among groups was much more limited than in the pluralist systems while the state role was more assertive and sustained.

Schmitter (1974) in his attempt to differentiate his thinking from pluralism did not make a realistic effort to engage in debate with the existent interest group theory (Jordan, 1993, Almond, 1983), and presented corporatism as a novel theory. The consequence of presenting corporatism as a new theory was to create debate on whether it was totally novel. The central corporatist purpose was to replace the pluralist model, building an alternative to the paradigm of interest politics (Jordan and Richardson, 1987). Grant (1989) wrote that corporatist theories were insufficiently distinct from the pluralist theories that they sought to replace; at best, they might be described as a subtype of pluralism (Almond, 1983, Grant, 1989). The corporatist model was seldom or never found in practice but Schmitter (1979) used it to underline empirically observable traits. Empirical examples of corporatism were much more difficult to find than had been claimed (Grant, 1989). Jordan and Richardson (1987) also found it difficult to implement the corporatist criteria because ambiguity on many of the key features of these criteria was the necessity of practical politics. Williamson (1985) noticed another issue not present in the work of Schmitter namely the bargaining between the different interest groups, which was a fundamental issue in relations between groups. Other corporatist writers such as Crouch (1983), Lehmbruch (1979) and Cawson (1985) did not address bargaining in a clear perspective.

2.2.1:3 Mesocorporatism

Wassenberg (1982) developed a new sub-concept: meso-corporatism. He examined the

role of collective actors not as peak class associations as in corporatist literature but as organisations that clustered around and defended the specific interests of sectors and professions (Molina & Rhodes, 2002). Their relationship of power dependence with state agencies could be exclusive but not necessarily tripartite in the manner of, say, peak employers and labour organisations (Cawson, 1985). Wassenberg (1982, p.85.) argued that corporatism could exist at three levels, according to the specialisation of the actors involved: *macrocorporatism* ("The peak institutions of the body politico-economic, like parliament, cabinet and the establishment of private peak associations") which represented the perspectives of Schmitter (1974); *mesocorporatism* ("The more or less institutionalised entity of complete industries, regional public authorities and the industry-wide and regional managerial machines of trade associations and labour unions") which was closer to the pharmaceutical industry and its chambers; and *microcorporatism* ("Individual corporate entities and establishments, local representatives of the trade unions and chambers of commerce and so forth, as well as to the lowest unit of politico administrative bodies") which represented the individual company. Traxler (1991) described three distinctive characteristics of meso-corporatism: first, the focus was on regions or economic sectors, rather than on the national economy as a whole; secondly, the policy targets were supply rather than demand of factors of production and consequently trade unions were less involved than in traditional corporatist agreements; thirdly, there was a significant gain in the relevance of entrepreneurs as actors within this mode of governance. Evans & Taylor (2001) confirmed that meso-corporatism was dominated by producer/provider interests as they had a propensity to engage in collective action which enabled them to participate in political exchange. The mesocorporatism perspective had a less ambitious understanding of corporatism as a sectional limited form with an empirical approach. The introduction of the meso- and micro-concept was vital in finally letting go of class

integration and cooperation as necessary aspects of the corporatist concept (Kalmes, 2001).

2.2.1:4 Corporate pluralism

Stein Rokkan (1966,) first used the term corporate pluralism. Kvavik (1976) and Heisler and Kvavik (1974) described it as a process of co-optation whereby groups were offered representation in policy-making circles in exchange for supporting the resulting policies even if the policy was not exactly close, or even very close, to what the group desired. In this model, pluralism was fuelled by the wishes of the groups to maintain their position within policy-making circles. This term was used to differentiate itself from 'competitive pluralism' where groups competed or to 'state pluralism' in which the state essentially imposed the public interest. Kelso (1978) reinforced this concept, opposing it to laissez-faire pluralism. He stressed the importance of cooperation between private groups and the government and them building networks to make decisions on policy between interest groups and government agencies. Kelso's (1978) model comprised of a political system broken in to a series of autonomous fiefdoms presided over by small coteries of interest groups that cooperated with the government in having an important role in decision making. The corporate pluralist model considered that there was interest group cooperation with the state but that there was no competition among interest groups. Jordan (1993) considered that in certain situations interest group competition did exist. Another concept similar to corporate pluralism was societal corporatism. For Jordan (1993), societal corporatism was a re-labelling of the corporate pluralist concept. Martin (1983) introduced in societal corporatism a new perspective where he stated that under societal corporatism the government and groups were in a bargaining relationship varying only in degree from pluralist forms.

2.2.2 Interest Groups theory

Under the different models of corporatism and pluralism, the formation of interest groups might be regarded as a result of a complex interaction between a number of specific social and political conditions; nevertheless internal conditions of the groups also played a role in the formation. Olson (1965) and Salisbury (1969) changed the perspective of interest group theory by bringing attention from external to internal interest group problems. Olson (1965), in the “Logic of Collective Action”, criticised the pluralist assumption that groups automatically emerged to reflect and defend common interests. Olson's (1965, p.24) key proposition was that “rational, self-interested individuals will not act to achieve their common or group interests”. Olson (1965) declared that rational individuals would decline to contribute to the costs of collective action and thus would free-ride unless there was coercion to force them to do otherwise (Maloney & Jordan, 1997). These organisations should have the authority and capacity to be coercive or have a source of positive inducements that they can offer the individuals in a latent group (Olson, 1965, Kavanagh and Jones, 1991). The rational potential member would allow others to bear the financial and time costs involved (Jordan and Richardson, 1987). Olson (1965, p.34) differentiated two types of incentive- selective and collective- and stressed that “Only a separate and selective incentive will stimulate a rational individual in a latent group to act in a group oriented way”. Members became active in groups not in pursuit of some collective good, which would be available to them irrespective of membership, but because of selective incentives of immediate and personal benefit (Jordan and Richardson, 1987). Olson (1965) focused on two factors, namely group size and social pressure. His idea was that the benefits of lobbying diluted with an increasing number of group members. It was more likely that small groups were able to overcome the free-riding problem if group

formation was to be expected at all (Becker, 1983). Moreover, social pressure or coercion might be a means of inhibiting free-riding. As it was more easily exerted in small groups, this aspect also tended to increase the likelihood that if interest groups emerged then they were small. Lobbying, for Olson (1965), was a by-product of large economic groups that obtained their strength and support because they performed some function in addition to lobbying for collective goods. This assumed that the provision of selective incentives was central to membership decisions and that this sort of membership incidentally provided the resources for lobbying for collective purposes. Walker (1991) disagreed with Olson's view as he declared that for groups pursuing broad public goods then selective material incentives were not likely to be available. Maloney & Jordan (1997) were also critical of Olson's view as they observed the proliferation of public interest groups. The by-product explanation was unconvincing; though material and selective incentives were found in this area it seemed unlikely that they were central to the joining decision. Kimber (1981) pointed out that the rational choice for a member of a group was not whether he/she should pay or free-ride, as Olson (1965) proposed, but if there was a certainty or uncertainty regarding the supply of the good. If the supply of the good was uncertain, the individual member should join the group. If the supply of the good was certain, free ride was the best option. Rothenberg (1992) noted that potential group members did not have perfect information and so, believing the supply of the good to be uncertain, would participate.

Salisbury (1969) presented another perspective where he demonstrated that organisational entrepreneurs marketed group membership on the basis of selective non-policy goods rather than just collective policy benefits (Browne, 1990). The group emergence/maintenance issue was regarded as an exchange situation in which entrepreneurs invested in a set of benefits which they offered to members at a price,

namely membership (Jordan & Richardson, 1987). Salisbury (1969) suggested that lobbying behaviour by group leaders was related to the leaders' personal choice and values and not to the members' demands. Walker (1983) introduced the concept of *patronage* as means of maintaining the groups, a concept that was not considered by Olson's (1965) approach. Groups were funded from public or private resources. The pharmaceutical industry in the USA funded advocacy groups as lobbying instruments (Public Citizen, 2001). Jordan and Richardson (1987) found the *patronage* concept empirically relevant but considered that it had been neglected. Moe (1980) applied Olson's approach to economically interested groups where it fitted better than in other sectors such as religion or social. Moe (1980) in his research also confirmed Olson's proposition that lobbying was a by-product and that selective incentives were the services supplied to members. Moe (1980) was less deterministic than Olson about what was individual logical behaviour as the individual might have imperfect information about the issue. The individual would choose according to the degree of information acquired and his/her values (Jordan and Richardson, 1987). Group leaders could play an active role guiding individuals in their decision to become a member by providing biased information (Maloney and Jordan, 1997).

Salisbury (1984) made a fundamental amendment to the pressure group literature by arguing that interest representation was dominated by institutions such as corporations and local government. He outlined that the classic view of the interest group omitted individual corporations, state and local governments, universities, think tanks and most other institutions of the private sector (Jordan and Richardson, 1987). As Salisbury (1984) recognised, the nature of these non-membership-based interest groups was important in the lobbying of Washington. Lindblom (1977) emphasised that a huge amount of corporate funds go to lobbying and other forms of corporate communication

with public officials. Scholzman (1984) commented over the disproportionate presence of business interests in Washington. Grant (2002) noted that business interests could have a significant input on the decision-making process. Moloney and Jordan (1996) also noted the interaction of corporations with government decision circles. Howell (2004) referred to this issue saying that they were the type of organisation whose political task was to reflect the interests of the economic or occupational section that they represented. Kirchner (1980) added that they were organisations that tried to influence the policy of public bodies towards their own chosen direction and they represented a number of similar groupings or both national groupings. Hudson (2002) stated that, for corporations, lobbying politicians was a worthwhile activity. Richardson's (1993, p.1) broad definition of pressure groups would also apply to corporations and the pharmaceutical industry. An interest group was "Any group which articulates demands that the political authorities in the political system or sub-system should make an authoritative allocation. These groups do not seek to occupy the position of authority". Woll (2006) noticed that the term 'interest groups' excluded firms and their political influence. As this research studied lobbying by pharmaceutical companies, the approach of Woll (2006, p.465.) was followed: "Lobbying is all the activities by private actors aimed at influencing political decision-makers", including firms as 'actors' but not as 'interest groups'. Pharmaceutical companies and the pharmacopolitics managers were considered lobbying actors. Coen (1997) showed that individual firms were important political actors and studies focused increasingly on new groups and *ad hoc* alliances rather than on traditional interest groups. Woll (2006) stated that different authors tried to study who was in position of influencing the policy process. Crombez (2002), tried to identify the phases of the policy process where lobbying would be effective. Eising (2004) studied the reasons for using different channels or representation and Bouwen (2002) researched the conditions that enabled

private actors to gain access. Grant (1989) studied the insider/outsider lobbying strategies. He remarked that insider groups had a better chance of influencing government policy. Grant (1989) classified 'insider' types dependent on their relationship to government and their lobbying strategy. He also classified outsider groups and emphasised the strategy of ideological outsider groups that did not accept the possibility of achieving change through the existing political system. They do not abide by the rules and were excluded from the consultative process.

However, in spite of these studies mentioned above, lobbying cannot be understood without looking at the context in which interest groups were trying to act. US lobbying differed from EU lobbying at the supranational level on political philosophies (Howell, 2004). Moloney (1996) stated that American lobbying practices were inappropriate in the UK and Europe. Woll (2006) presented a table that depicts the different styles of lobbying in the USA and in the EU at a supranational level.

Table 2 Trends in US and EU lobbying

| | United States | European Union |
|---|--|--|
| <i>Organization of interest representation:</i> How do individual actors organize? | Direct representation, issue-specific coalitions, which may take the form of longstanding associations | National and sectoral peak organizations, which tend to form European platforms, recently also direct representation |
| <i>Instruments:</i> What methods and resources are available? | Financial contributions, legal representation, formal and informal consultation, media and grass-roots tactics | Mainly consultation, both formal and informal, some legal advice, outsider strategies limited |
| <i>Policy process target:</i> Where and when do lobbyists decide to act? | From contributing to the formulation, affecting revisions to blocking decision | Lobbying on formulation and revision at supranational level; decision lobbying pursued national route |
| <i>Characteristics of consultative lobbying:</i> What kinds of relationships develop between public and private actors? | Competitive, fragmented, both short term and long term | Long-term and trustbased, multi-level strategies |
| <i>Style of consultative lobbying:</i> How do lobbyists express their demands? | Defensive, direct, focus on immediate interests | Constructive, cautious, consensus-oriented |

As pharmaceutical lobbying in Argentina existed in another context the main issues indicated by Woll (2006) in the table above have, in the conclusions chapter, been compared to the substantive theory.

The formal macro-theory of lobbying described the different political theories of interest group participation in the political process and provided the basis for the development of interest group formation theory. Within this framework, the theories of pluralism, corporatism and its variations provided the basis to understand how interest groups acted in a democracy. The researcher explored these theories to identify which model was predominant in the pharmaceutical industry scenario in Argentina. Interest group theory was discussed to address the perspective of the lobbying activities of the

pharmaceutical industry as an interest/pressure group and of individual companies as lobbying actors. The different lobbying styles were also addressed.

One of the aims of this project was to address the question of how pharmaceutical lobbying was carried out. To analyse the process of pharmaceutical lobbying and answer this question, the researcher explored the formal meso-theory of lobbying and this provided a logical framework of how lobbying was exerted. The researcher has described this theory in the following section.

2.3 *Formal meso-theory of lobbying: lobbying models*

2.3.1 Introduction

This section includes the theory of lobbying based on academic mathematical models, most of them based on the game theory and Nash's equilibrium. The meso-theory of lobbying provided a logical framework with clear definitions so that the researcher was able to identify the different stages in the lobbying process. As one of the research questions was 'How pharmaceutical companies in Argentina carry out lobbying', the theory of lobbying based on the game theory provided the foundation to compare the formal theory with the substantive. The review of the literature showed first the reduced form lobbying models and then the two main channels of influence described by Bennedsen and Feldmann (2001) which exist in parallel: contribution payments and the transmission of information through lobbying. Both approaches were the origin of different models by different authors and they were analysed.

2.3.2 Different models of the theory of lobbying

For this research, the researcher considered the lobbying conceptual models based on the game theory. Election lobbying models were not the subjects of this research so they were not included.

2.3.3 Reduced form lobbying models

The reduced form lobbying models were simple and they did not consider certain aspects of individual behaviour in the process of lobbying.

The *regulatory approach*, first proposed by Stigler (1971) and formalised by Peltzman

(1976), assumed that the politician set a policy in order to maximise the weighted sum of special interest's utility and aggregate welfare. There was an underlying lobbying process that was not explicitly analysed. Hence, the regulatory approach focused on the determination of the policy outcome given that some kinds of special interest activity led to a policy bias in favour of a certain group. Peltzman (1976) applied this model to price regulation in which the interest group increased prices and yet the consumers preferred low prices. Hillman (1982) used it for trade policy in an import competing industry - the world market price of the good decreased and the official increased the tariff to protect the producer lobby in its own country.

The *policy formation approach* by Becker (1983): This model chose contribution payments by two opposing interest groups as the central issue. It focused on the lobbying process, but did not consider the decision problem of the politician. Instead, it introduced an "influence function" which stated how realised policies depended on the interest groups' contribution payments. The approach determined the lobbying efforts endogenously and derived comparative results for the two interest groups. Groups chose their contribution levels non-cooperatively (Becker, 1985). The political decision had only redistributive effects. One lobby gained from redistribution via subsidies and the other lobby lost because subsidy payments were financed through taxes. It also analysed the size of interest groups following Olson's (1965) approach that, in larger groups, members had a greater incentive to free-ride. Pecorino (1997) applied this model in the context of international trade policy and stated that lobbying expenditures increased in the short run if industries faced an exogenous decline, for instance the decrease of the world prices. Lobbying caused tariff increases and the lobby had higher profits and the sector expanded.

2.3.4 Contribution payments to an incumbent government

This section focused on the *incentive motive* of lobbying. Contributions provided incentives for the politician to deviate from the best policy choice. In contrast to the reduced form models, these models fully specified the objective function of both the politician and the interest groups. This allowed for an analysis of strategic interaction between interest groups and the politician. Moreover, interest groups' objective functions resulted from a fully specified microeconomic general equilibrium model and were not made ad hoc. This allowed further insight concerning the resulting equilibrium policies. The models of this section made use of theoretical results from common agency theory, which comprised situations in which a set of principals influenced the decision of a common agent (Bernheim and Whinston 1986a).

2.3.4.1 Common agency theory

Beginning with the contributions of Bernheim and Whinston (1986a), the common agency theory developed an analytical framework with which to tackle a variety of important problems such as menu auctions (Bernheim and Whinston, 1986a), public good provisions through voluntary contributions (Bernheim and Whinston, 1986b), or policy formation under the influence of competing lobbying groups (Grossman & Helpman 1994). Lately, other applications had been introduced in the context of environmental regulation such as Aidt (1998), where interest groups lobbied for tariffs on pollution.

The common agency framework was characterised by an agent and a set of principals (Bernheim and Whinston 1986a). The agent chose an action among a feasible set of actions which affected his/her own utility and that of the principals. As the individual utility level of all principals depended on the action of the agent, the principals faced an

incentive to influence the agent's choice. Each principal made a contingent contribution offer, an individual payment function, which established money rewards to the agent for each possible action he/she might choose. Common agency models were based on the fact that several principals designed non-cooperative contribution schedules for a common agent.

2.3.4:2 Common Agency Lobbying Model

The first application of the common agency framework to a lobbying game was by Grossman and Helpman (1994). Lobbying applications fitted well into the framework of the common agency theory. Rodrik (1995) pointed out that the great advantage of this model was that it provided clear-cut micro foundations for lobbying and its effects in a tractable and fairly general setting. The politician (the agent) decided about a policy which affected the payoffs to the principals (the interest groups) who in turn tried to influence his/her choice. In the first stage of the game each lobby decided on a non-negative contribution function, that was a contribution offer to the politician, stating how much money would be paid for each alternative policy realisation. In the second stage, the politician observed these offers, determined the policy and collected the respective money offers. The politician might well have preferences about the policy. For instance, a benevolent politician would prefer the policy that maximised aggregate welfare. Any deviation then reduced aggregate welfare and thereby his/her utility level. Contribution offers by special interest groups served to compensate the agent for any deviation from the welfare maximising policy. On the other hand, if the politician was completely opportunistic he/she cared only about contributions and not about the policy itself.

The common agency lobbying model introduced by Grossman and Helpman (1994)

failed to consider important elements that cannot be disregarded. Mitra (1999) and Rama & Tabellini (1998) found that this model ignored the fact that interest groups faced incentives to organise and cooperate if they had a common interest. Grossman and Helpman's (1994) model always assumed a non-cooperative game between interest groups. Maggi and Rodriguez Clare (2000) and Dixit (1996) considered that the politician had only a single policy instrument and did not have a wide choice of policy instruments. The model considered only one agent, which meant one government, and abstracted from the possibility of the interaction with another government (Grossman and Helpman, 2005).

2.3.4:3 Common agency lobbying model with cooperation between interest groups

Rama and Tabellini (1998) analysed the incentives of labour and capitalist interest groups to cooperate. Tariffs and minimum wages made up the available policy. The authors derived conditions such as cooperative lobbying leading to higher payoffs than non-cooperative lobbying. Howell (2004) confirmed this statement saying that to ensure effective lobbying it was necessary to build coalitions. This tended to be the case if the sum of the joint payoffs between the government and any of the interest groups was high compared to the payoff to a coalition consisting of all interest groups and the government. Intuitively, if the government achieved a high joint payoff with any of the two interest groups alone it would be able to play the interest groups off against each other and benefit from a firm conflict of interests between interest groups (Rama & Tabellini, 1998). In contrast if the joint payoff to a coalition of all players, that is the government and both interest groups, was high then there was an interest to include all relevant groups in the political process even if interest groups behaved non-cooperatively (Laussel and Le Breton, 2001). Aidt (1997) also analysed cooperation between interest groups and stated that there was always scope for cooperation because

otherwise interest groups engaged in costly counteractive lobbying. Graziano (2001), Hula (1999) and Hojnacki (1997) remarked that interest groups often entered into coalitions to reduce the cost of lobbying for a certain purpose. However, cooperative lobbying violated the autonomy to which groups aspired (Hula, 1999) and there was the possibility of members defecting as a result of working with other interest groups. Therefore, as Almeida (2005) noted, interest groups would prefer to enter into coalitions with ideologically similar groups. Maggi and Rodriguez Clare (2000) and Dixit (1996) considered that in this model of cooperation between two interest groups, the official did not have a wide choice of policy instruments and it abstracted from the possibility of the interaction with another government (Grossman and Helpman, 1995). Building coalitions to carry out lobbying was an important issue in this research as pharmaceutical companies faced incentives to perform cooperative lobbying when the target was the government.

2.3.4:4 Common agency lobbying model with two agents

The common agency lobbying model presented by Grossman and Helpman (1994) assumed a small country. Grossman and Helpman (1995) in another paper extended the basic lobbying model regarding this aspect and considered strategic interaction between two governments. This extension was relevant to the common agency model more generally: the government now constituted two agents that faced influence from distinct sets of principals (the interest groups) in their home countries. Countries traded with each other, which established the link between domestic tariff structures. As a consequence governments could no longer independently respond to lobbying activities but needed to take strategic interactions with the other government into account. The model assumed that interest groups influenced only their domestic governments but not the government of the foreign country. Each lobby's payoff now depended on the trade

policies of both countries and not only on the domestic country. Accordingly, a contribution schedule mapped each domestic tariff structure into money offers for any given trade structure of the foreign country. The lack of a choice of policy instruments was problematic in this model (Maggi and Rodriguez Clare, 2000 and Dixit, 1996).

2.3.4:5 Common agency lobbying model with choice of different policy instruments

Several authors extended the common agency lobbying model to the choice between various policy instruments. Rama and Tabellini (1998) analysed two interest groups that competed with respect to one policy variable and coincided with respect to another. The economy consisted of two sectors. The unorganised sector produced only with labour. The import competing organised sector produced with labour and capital. Factor owners of the latter sector organised along factor lines, i.e. there was a lobby of workers and a lobby of capitalists. The available policies were a price increasing tariff, which benefited the workers and the capitalist alike, and a minimum wage in the import competing sector, which increased the payoff to the workers at the expense of capital owners. The authors showed that a tariff redistributed income towards capitalists and led to allocation inefficiencies. Other contributors included Dixit (1996), who incorporated production and consumption subsidies/taxes and heterogeneous group sizes into the model. Maggi and Rodriguez Clare (2000) analysed the choice between voluntary export restraints, import taxes and import quotas in a trade model and derived conditions for the use of each instrument. All these authors failed to discuss the relationship between the degree of competition and policy efficiency. If competition among interest groups was weak then the ability to lobby was a benefit and instruments that were more efficient decreased compensation payments. In contrast, if competition among interest groups was severe then the ability to lobby was a necessary duty in order not remain unheard in the political process. In this case interest groups preferred

inefficient means because this reduced obligatory compensation payments (Baldwin & Robert-Nicoud, 2002).

2.3.4:6 Common agency lobbying model with entry decision

Mitra (1999) abstracted from incentives to free-ride within interest groups and presented another model. He extended the basic lobbying model and analysed the entry decision of interest groups and not the exit decision. These decisions determined the equilibrium number of interest groups and the degree of lobbying competition. Those interest groups that decided not to enter anticipated that the cost of organisation exceeded its net benefits whereas those who entered anticipated that the degree of lobbying competition was small enough so that the benefit of entry exceeded its costs.

2.3.4:7 Incentives to free ride and to cooperate

Olson (1965) was the first author to indicate that interest groups had an incentive to free ride and assumed that free-riding was more likely to happen in large groups. Kimber (1981) made an addition to the work of Olson and stated that interest groups would free-ride when the supply of the collective good was certain. Hence incentives to free-ride within interest groups might result and the question arose under which conditions it might emerge. Damania and Fredriksson (2000) focused on incentives to free-ride in a setup where two interest groups followed a common interest. Pharmaceutical companies might free-ride and not incur the costs of lobbying when other companies lobbied a common interest. Damania and Fredriksson (2000) stated that each group might abstain from lobbying, lobby alone, or form a coalition with the other lobby. The authors stated conditions whereby free-riding on the other firm's lobbying activities, joint lobbying, or unilateral lobbying occurred in the state game. If the game was repeated infinitely, cooperation might result even if free-riding was the optimal behaviour in the state game.

Cooperation was implemented through trigger strategies that let each firm cooperate as long as the other one did so too. Cooperation was more likely if the short term benefit of defection was small relative to the discounted future benefits of cooperation.

2.3.5 Transmission of information

Politicians had an incentive to listen to interest groups when they were imperfectly informed and interest groups possessed better information about the relevant policy (Neske, 1997). Interest groups might be better informed either because they had specific expertise in certain policy fields or because they had investigated and acquired the relevant information about the subject (Koepl, 2001). This situation created the information motive for lobbying. Lobbying gave politicians a chance to improve their decisions in this context. This situation was strongly related to the "bounded rationality" concept developed by Simon (1955, 1956) against the rational paradigm concept in neoclassical economic theory. The rational paradigm assumed that economic agents (e.g. households) were decision makers who were fully rational in choosing their actions given their perceived feasibility constraints (e.g. a budget set) in order to optimise some objective function. The implications of this assumption surfaced when the hypothesis of rationality was extended to a dynamic economic environment where agents had to form expectations about the future realisation of certain economic variables (Aumann, 1997). The term bounded rationality (Simon, 1955) was used to designate rational choice that took into account the cognitive limitations of both knowledge and capacity. It was concerned with the ways in which the actual decision-making process influenced decisions (Sent, 2005). Adapting bounded rationality to lobbying we saw officials faced with uncertainty about the future policies and an inability to incur costs in acquiring information. These two factors, thus, limited the extent to which officials could make a fully rational decision. Simon (1955) claimed

they had only "bounded rationality" and officials were forced to make decisions not by "maximisation" but by "satisficing" based on the information provided by the interest groups. Rötheli (2005) added that the tendency of individuals, in this case officials, to under-invest in information in situations where they had to pay for it could lead to significant welfare losses. Simon (1972) stated that individuals were content with a certain level of achievement and indifferent to gains beyond that. That is, they did not attempt to optimise beyond a personal level of satisfaction. Aumann (1997) criticised Simon for leaving bounded rationality in what he considered to be a state of distress; much of Simon's work was more conceptual than formal and thus impeded its progress. Sargent (1993) and Aumann (1997) tried to use bounded rationality in neoclassical economic game models against Simon's intentions (Sent, 2005). Arrow (2004), Kahneman & Tversky (1974) used bounded rationality in the field of behavioural economics regarding the question of how people made judgments on the basis of incomplete and imperfect information. However, these authors differed from the original approach of Simon as they departed from the rational paradigm and then analysed variations of it - the opposite of Simon's framework that departed from the concept of bounded rationality to analyse the individual decision-making process (Sent, 2005).

For the purpose of the study the researcher has addressed the models of transmitting information as communication models.

2.3.5:1 The basic communication model

The models of Potters and van Winden (1992), and Ainsworth (1993) were basic communication models. There existed two states in the world whose realisation was not known to the politician but was known to the lobbying group. The politician had prior

beliefs about the probability that a certain state occurred. Furthermore he/she implemented one of the policy alternatives. The payoff to the politician was high if he/she implemented the correct policy in each state and low if he/she implemented the wrong one. Hence, the task of the politician was to choose a correct policy under uncertainty. A single lobbying group guided the politician in his/her choice. This lobbying group observed the realised state of the world and had perfect information (at least in the model). It could inform the politician about the realised state by sending information. The politician, who observed only the information but not the true state of the world, anticipated that sending information was only worthwhile for certain types of interest groups. He/she updated his/her beliefs accordingly. The payoff to the lobby depended on the realised state of the world and might conflict with the interests of the politician. The politician had to decide whether or not to trust the information received by the lobby group. The model incorporated the previous belief of the politician about the correct policy and the classification by the politician of the interest groups into good and bad types.

This model abstracted from the issue that sometimes 'good' and 'bad' type interest groups cooperated so that the pay off to the politician was negative and he/she deviated from the decision that maximised welfare. Another issue that this model introduced was the subjective element of the moral classification of determining lobby types- the politician being responsible for deciding which were good and which were bad.

2.3.5:2 The communication model with lobbying competition

Austen-Smith and Wright (1992) focused on the aspect of counteractive lobbying of two interest groups with opposing interests. The politician decided between two policy alternatives. Based on his/her prior belief he/she chose the policy of the benefited group.

This gave the opposing group incentives to induce a policy deviation through communication which in turn might lead to counteractive lobbying of the benefited group aimed at preventing any policy deviation. The occurrence of lobbying depended on the extent of verification costs for the politician and the cost of information acquisition for the interest groups (Rasmusen, 1993). If costs of verification were low then the politician was always capable of verifying the truth. In the case that verification costs were high the politician would only verify when he/she received conflicting information. If the opposing lobbying group had the opportunity to send information to deviate the policy decision of the politician the benefited group could send contrasting information depending on the investigation costs and the effect of the policy deviation on its own interests.

Austen-Smith and Wright's (1992) model introduced verification costs for the politician and investigation costs for the interest groups. It simplified reality as there were only two opposing interest groups, not a number of interest groups, and it did not consider a situation when interest groups cooperated.

2.3.5:3 Models of mass movements

The analysis of Lohmann (1993) deviated from the basic communication model and yielded some interesting new insights concerning interest groups' incentives to free-ride and the effect of preference dispersion on the formation of mass movements. Again the politician decided between two given policy alternatives which were now elements of a continuous policy interval. There were a finite number of lobby groups that were distributed along this interval. They were characterised by single peaked preferences about the policy in question and each group preferred the policy alternative which was closer to its ideal point. The distribution of the groups along the interval was known to

the politician. He/she was benevolent and sought to maximise welfare through implementation of the median policy.

Each group (but not the policy maker) received imperfect information about the state of the world so that it decided to send costly information to the politician, which was interpreted as a vote for a certain policy alternative. The politician observed the amount of information received by the different groups, updated his/her belief concerning the preferred policy of the median voter and decided accordingly. Each group compared the lobbying costs with the expected benefit, which depended on the utility difference between the policy alternatives weighted by the probability that the lobbying effort was essential for the politician's choice.

Lohmann (1995b) introduced the concept of extremists and moderates in her model. Extremists were defined as groups that preferred a policy alternative independent of the received signal. Extremists who preferred a certain policy always had an incentive to lobby, whereas extremists preferring the policy alternative did not. Lobbying by extremists conveyed no information if the politician knew that it was from extremists. In contrast, the preferred policy of "moderates" critically depended on the received signal. Those who received a signal in favour of the policy faced incentives to lobby whereas the others did not. Hence, only lobbying by moderates conveyed information to the politician because their decision to lobby revealed information about the received signal. But not every group facing incentives to lobby in fact did so because incentives to free-ride existed. Lobbying costs increased the moderates' incentive to free-ride. If lobbying costs were high then only some moderates facing incentives found it worthwhile to incur those costs. Therefore some moderates sent messages while some would free ride.

Lagerlof (1997) extended this model and assumed that the interest group was imperfectly informed. Investigation by the lobby implied that it learnt the true state of the world with an exogenously given probability. The lobby might be forced to acquire information if the politician expected it to do so; so that the lobby might be trapped in information acquisition which reduced its expected payoff but increased expected aggregate welfare.

This model assumed that the politician had precise information about the interest groups' preferences in the continuous policy interval. It did not accept that the lobby lied about its preferences. It also forced the politician to make a judgement about which interest groups should be categorised as extremists and which as moderates.

2.3.5:4 The communication model with access buying

Communication costs served as an access device which informed the politician about the benefit of granting access to certain groups. Lohmann (1995a) used a slightly modified set-up of her model of mass movement to focus on contributions as an access device. In this modification, each lobby either sent one or two costless messages, indicating which policy alternative it preferred, or no message at all. Lying was possible. The politician listened only to those messages that were accompanied by access contributions paid for by 'those who have something to say'. Austen-Smith (1998) presented a similar model where only one interest group gained access to the politician although all interest groups made contributions to have access. This model gave power to the politician who selected the interest groups that he/she wanted to listen to.

2.3.6 Lobbying model with a mixed approach

The literature on lobbying divided into two broad strands as the preceding sections indicated: lobbying was analysed either as contribution payments or as a means of transmitting information. Bennedsen and Feldmann (2001) introduced the first mixed approach with both components. Their new model focused on the instrument choice of lobbying. They assumed that an interest group might influence a political decision in two independent ways. Firstly, it might engage in costly information acquisition and transfer the result truthfully, as was known from the communication literature. Second, the lobby determined contribution payments that compensated the politician for a deviation towards its preferred policy choice. The question that arose was which type of lobbying the interest group preferred and how these instruments affected each other. Bennedsen and Feldmann (2001) showed that interest groups with intense preferences and high stakes in their preferred policy also preferred to offer contributions rather than the acquisition and provision of useful information. In these cases, information played a subordinate role.

The formal meso-theory of lobbying has been explored in this section. The theory provided two main channels of influence to explain how lobbying was carried out: contribution payments and transmission of information. In the first one, interest groups or lobbying actors based their lobbying on contribution payments. These contributions aimed to influence the decisions of officials so that they deviated from the best policy and chose the option that most benefitted the interest group/ lobbying actor. The second channel of influence relied on the concept of asymmetric information. Politicians faced capacity constraints that gave them informational disadvantages compared to interest groups/lobbying actors - they had to rely on the information provided to them in order to take a decision. Bennedsen and Feldmann (2001) presented a model that integrated

both channels of influence- transmission of information and contribution payments. Building coalitions proved to be useful when interest groups/lobbying actors joined to lobby the government. Companies might also have preferred to free-ride on the others' lobbying efforts when they had a common interest so that they did not have to incur in the costs of lobbying.

The next section focuses on the formal micro-theory of lobbying which explains the application of lobbying carried out by the pharmaceutical industry in the USA. There was no literature on pharmaceutical lobbying in Argentina so the researcher chose the USA because the market was the most similar to the Argentine one.

2.4 Formal micro-theory: Pharmapolitics, pharmaceutical industry's influence on politicians and managed care settings

2.4.1 Introduction

The micro-theory of lobbying was considered in order to illustrate the peculiarities of pharmaceutical marketing and pharmaceutical lobbying so that the reader had an understanding of the characteristics in these markets. The formal micro-theory of lobbying explained the application of pharmaceutical lobbying in concrete situations. The micro-theory of lobbying has been used to review the two main activities of pharmacopolitics (Quiñones, 2002):

- a) Lobbying congress and public officials.
- b) Lobbying HMO officials.

The literature research was focused on the how the pharmaceutical industry applied lobbying in the two main activities mentioned above. There was no literature on pharmaceutical lobbying in Argentina so the researcher chose to look at the USA because it was most similar to the Argentine (Vasallo, 2002).

Vincent (2003) wrote a comparative work on the major pharmaceutical markets and compared them to Argentina. In this work the researcher identified the distinctive features of each market and designed the following table for analysis:

Table 3 *Comparison of Health Care Systems (adapted from Vincent 2003)*

| Country | National Formulary | HMO Formulary | Prices | Co- payments | Health Care Coverage | Health as Public/private good |
|-----------|-----------------------|------------------|--|---------------------------|-------------------------|-------------------------------------|
| UK | No | Yes | Control on generics / research products by reimbursement | Low | Whole population | Public |
| Germany | No | No | Controlled | Low | Whole population | Public |
| France | No | No | Controlled by reimbursement | Depends on the product | Whole population | Public |
| Spain | No | No | Controlled | Low | Whole population | Public |
| USA | No | Yes | Free | High | 20% without coverage | Private |
| Argentina | Yes | Yes | Free | High | 35% without coverage | Private |

The first important difference between the European health care systems and the Argentine and American is the philosophical conception of health care (Vasallo 2002). Health care in Europe is a social good where the whole population has the right to access to this social good (Saltman, 2002). In the other two systems that was not the

case; health care was a private good and those who could pay could have access. Vazquez (2002) emphasised that access to health care in Argentina was dependent on employment status (employee/employer contributions) or the ability to pay. People without coverage depended on public hospitals with long waiting lists and improper conditions (Neri, 2002). For Puig Junoy (2005) the big difference between the two models- the European and the American- was the degree of price control. European countries tended to control the prices of new and existing products by various mechanisms; reimbursement, reference prices or direct price control. In the USA and in Argentina companies had freedom to set prices. Vincent (2003) made another distinction. In European countries, except for the UK, there were no restricted formularies. A formulary lists the drug or products for which reimbursement will be paid (Dranove, 2003). The use of formularies has been explained later in this section. Vincent (2003) noted that in the USA, as in Argentina, all HMOs had formularies. In Argentina there was additionally a national formulary that indicated the drugs that should be covered by all HMOs. This national formulary, called Programa Médico Obligatorio (PMO), was restrictive. Nevertheless, each HMO could decide whether to include more than these drugs in its formulary if it considered it necessary (Tobar, 2002). These main differences between Europe and Argentina prompted the researcher to use the US approach and literature for this study.

In this section, the researcher first explained the significance of pharmacopolitics as it was the term used in Argentina for the pharmaceutical industry's lobbying activities. Secondly, the researcher described how lobbying of public officials and legislators was carried out in the USA. The researcher showed the different lobbying strategies and tactics that were used by pharmaceutical companies in the USA and depicted the motivations for this lobbying. This section also showed how the pharmaceutical

industry carried out cooperative lobbying through the American Chamber (PhRMA). Thirdly, the researcher described the lobbying exerted on HMO officials by pharmaceutical company managers. The researcher explained the managed care system and the development and use of formularies for cost containment purposes. This explanation was very important in order to illustrate for the reader the different components of pharmaceutical lobbying and so that it was easier to understand the substantive theory when the different elements were mentioned.

2.4.1.1 Pharmacopolitics

The term *pharmacopolitics* or *pharmapolitics* has been defined as the activities performed by the pharmaceutical industry aimed at influencing government, public officials and Health Management Organisations (HMOs) in order to get a competitive advantage in the market (Quiñones, 2002). There was no research on this topic in Argentina and the first mention of this term in the literature was by Cerasale (2001), who claimed that it had become a popular word together with pharmaeconomics but instead of explaining its significance he continued the paragraph describing the advantages of pharmaeconomics. The second mention in the literature was by Tobar (2002) referring to pharmacopolitics as the twin sister of pharmaeconomics but again there was no explanation of its significance and scope.

Redwood (1997) referred to pharmacopolitics as the policy implemented by the pharmaceutical industry according to the political environment, regarding innovation, location (Redwood, 2002) and cost-containment procedures. Redwood focused on the cost-containment policies implemented by the health bureaucracies and described its flaws. This definition of pharmacopolitics did not correlate with the definition of pharmacopolitics accepted in Argentina (Quiñones, 2002); Redwood's (2002) definition

described the influence of the political scenario in the decisions taken by the pharmaceutical industry.

2.4.2 Lobbying of Congress and Public Officials in the USA

2.4.2:1 The perspective of the pharmaceutical industry

No paper had been written by the pharmaceutical industry about its lobbying activities in the USA. The only written information was the speeches given by Holmer (2002, 2004), President of the Pharmaceutical Research and Manufacturers of America (PhRMA), at its annual meetings (2002, 2004). PhRMA is the Pharmaceutical Companies Chamber in the USA; generic companies are not members of PhRMA. Generic companies being those that manufacture and sell copies of the products at a lower price when patent life has expired.

Holmer stated that the PhRMA strategy consisted of two different tactics:

1. Advocacy programs: Holmer's objective was to make PhRMA the premier advocacy organisation in the world. To achieve this objective advocacy programs were run from PhRMA's eight regional offices and PhRMA was represented in 50 state capitals by people from the Republican and Democrat parties. "These are representatives of local citizens, know the legislators well, and understand how our issues will be considered in their states" (Holmer, 20002, p.1). PhRMA also had six development people in the regional offices that contacted labour leaders, small business owners, physicians, nurses, pharmacists, minority groups, patients and patients' advocates. Alliances had been made with these groups aimed at achieving common goals.
2. Federal lobbying: The federal lobbying team of PhRMA amounted to 17 people.

These were the in-house lobbyists. Some former congressional staff were included in PhRMA's payroll eg Rodger Currie (Common Cause, 2001) appointed as one of the leaders of the PhRMA team of lobbyists (Holmer, 2002). Holmer (2004) stated that the team achieved outstanding results on the issuing of the new Medicare Law in December 2003. For the issuing of the law 952 lobbyists were hired by PhRMA, pharmaceutical companies and HMOs to do their bidding on Capitol Hill and the White House (Congress Watch, 2004).

In all his assertions Holmer (2002, 2004) denoted triumphalism with sentences like "But one organisation never loses and that organisation has hundreds of victories to its credit and zero defeats in the United States Congress and that is the pharmaceutical industry"(Holmer, 2002, p.1). Holmer showed the corporatist position of the pharmaceutical industry in a privileged relationship with the decision-makers in congress. The speech given by Holmer (2002), did not describe how lobbying is implemented or financed in Washington or on a regional basis but these topics have been well documented by several interest and pressure groups.

2.4.2:2 Research undertaken by Interest Groups

Common Cause (2001) and especially Public Citizen (2001, 2004) engaged in an extensive and thorough research describing the strategy, the resources used and the achievements of the pharmaceutical industry in Washington. Those two groups were mentioned by Richardson and Jordan (1987) as important public interest groups. Grant (1989) considered these groups as ideological outsider groups. It should be pointed out that even if the information was based on reliable data (since 1995 company expenditure on lobbying legally needed to be disclosed (Public Citizen, 2001)), the opinions of these groups were biased towards the objectives they defended. Sentiments

such as “This industry, however, racked up its successes at the expense of the American public” (Common Cause, 2001, p.4), or “Public Citizen believes that no bribes should be given to the drug industry” (Congress Watch, 2002, p.63.) were common so the researcher focused on the data presented rather than on the opinions enunciated. In the introduction of its report “America’s Other Drug Problem: A Briefing Book on the Rx Drug Debate” Public Citizen Congress Watch (2002, p.4.) stated, “Some readers may see a pro-consumer bias in the selection of facts. That bias may well exist”. Nevertheless, in the creation of the report, it stated, “We have used credible, independent sources and the most current data that we know of for each and every point we make” (Congress Watch, 2002, p.4.). These two groups fitted the pluralism model of democracy in which interest groups had access and were heard by government.

According to Public Citizen Congress Watch (2004), the pharmaceutical industry was one of the most potent political forces when it came to influencing legislation in Washington, confirming the corporatist privileged relationship of the industry in decision-making circles. The industry largely got what it wanted from politicians in Washington through lobbying by former congressional staff, campaign contributions, issue advertising, funding front groups and conducting grassroots lobbying. Common Cause - a citizen’s grassroots lobby dedicated to making government more open, honest and accountable at the national, state and local levels- declared in its report “Democracy on Drugs” (Common Cause, 2004) that according to federal lobbying reports PhRMA and its member companies spent at least \$72.6 million on lobbying congress, the White House and federal regulators in 2003. This information did not tally with the estimate of \$108.6 million spent in 2003 mentioned in Public Citizen Congress Watch Report (2004). Public Citizen Congress Watch reports had a sound methodology and a complete list of references. Common Cause reports had very few references and the

methodology of obtaining the information was not described. For that reason Public Citizen was considered for raw data and Common Cause information and other sources were used to complement this information.

2.4.2.3 Structure of the industry's lobbying

Public Citizen Congress Watch (2004) stated that in 2004 the industry hired 824 lobbyists. Of those 405 were 'revolving door lobbyists' as they were previous members of congress, staff or executive branch employees and had special access to the current members of congress. Moloney (1996) commented that UK lobbyists had the same background. Of the remaining 419 lobbyists, (Public Citizen Congress Watch, 2004) 136 were in-house lobbyists for PhRMA. In 2003, in terms of lobbying expenditure, the top 20 companies all spent more than \$1m and eight of the top ten were American. This demonstrated the acceptance of American companies towards the activities of lobbying Congress and the government.

During the 2003 election cycle the prescription pharmaceutical industry gave \$3.4 million towards the Bush campaign. Democrat hopeful Kerry also turned to two top fundraisers who worked for the drug industry: David Leiter and Mac Bernstein collected funds for his campaign (Congress Watch, 2004). The industry increasingly allied itself with the Republican Party, which it perceived as more supportive of its goals and which took control of Congress in 1995. Nevertheless, the pharmaceutical industry continued to cultivate some key Democrats such as Senator Joseph Lieberman and Senator Robert Torricelli of New Jersey, a state that had a high concentration of pharmaceutical companies. Contribution payments, as described by Grossman and Helpman (1994), were an important instrument used by the pharmaceutical industry in its lobbying of Congress.

2.4.2.4 Methods of lobbying

The methods of executing lobbying demonstrated a high degree of sophistication. The traditional method was to donate campaign contributions in the election cycle and since 1999 pharmaceutical manufacturers and HMOs have contributed some \$84.6 million (Congress Watch, 2004) to Bush's political campaigns. There was also an increase in unlimited donations, also known as soft money, to PACs (Political Action Committees) controlled by Party leaders. Forty one million dollars was devoted to four stealth PACs in 2002 to help elect a Congress sympathetic to the pharmaceutical industry's interests (Public Citizen Congress Watch, 2004). The pharmaceutical industry also contributed \$625,000 to the inauguration committee of President George W. Bush and thus established a relationship that later collected its rewards as Mitch Daniels (Eli Lilly) ran the Office of Management and Budget, Donald Rumsfeld (Searle) sat in Bush's Cabinet and a one time pharmaceutical industry lobbyist, Nick Calio, was Bush's chief liaison to Congress (Public Citizen Congress Watch, 2001).

Other vehicles that supported the pharmaceutical industry's lobbying efforts were the United Seniors Association, 60 Plus Association, the Seniors Coalition and America 21. According to Congress Watch (Public Citizen Congress Watch, 2004) they were sham interest groups sponsored since 2002 to oppose drug policies against the industry. Walker (1983) mentioned the use of these types of group and introduced the concept of *patronage*, which stated that there were some groups funded by the government or private interests to advocate specific interests. The objective of these stealth PACs, as enunciated in their websites, was to pursue basic consumer fairness in health care. Using these groups the pharmaceutical industry spent \$41 million in 2002 on advertising aimed at supporting or attacking candidates that might help or hinder the interests of the pharmaceutical industry. Citizens for Better Medicare, another PAC that

was replaced in 2002 by the previously mentioned groups, was the first PAC used by PhRMA. Its initial wave of advertising was the Harry and Louise campaign aimed at opposing the Clinton health care plan on Medicare in 1993-1994 (Public Citizen Congress Watch, 2002). The advantage for the pharmaceutical industry was that Citizens for Better Medicare spending was kept secret under Section 527 of the federal tax code, which covered groups whose purpose was to influence or attempt to influence elections. Shortly after Congress closed the 527 loophole, Citizens for Better Medicare became a different kind of tax-exempt group- a 501(c)(4) non-profit, which also permitted keeping spending secret. The four new stealth PACs now used by the pharmaceutical industry were classified under this category. They did not have to disclose contributors or spending details; PhRMA and the pharmaceutical companies however had to disclose spending on lobbying activities (Public Citizen Congress Watch, 2002, 2004). These kinds of tricks helped to preserve the anonymity of the pharmaceutical industry, although there were indications that showed the relationship between both parties.

In addition to the four stealth PACs the pharmaceutical industry also had close ties to the US Chamber of Commerce (Public Citizen Congress Watch, 2002) and the Department of Health and Human Services (Common Cause, 2004). The Secretary of the Department of Health and Human Services, Tommy Thompson, made an “unusual appearance” at Congress the night of the final vote for the new Medicare Law was taking place. According to National Journal’s Congress Daily, secretary Thompson lobbied members on the House floor during the final three hour roll call vote on the Medicare reform bill.

2.4.2:5 Strategy

The pharmaceutical companies' strategy regarding lobbying was concentrated on three issues: protect themselves against competition, preserve freedom in establishing prices and introduce tax breaks that improved the bottom line.

Protect themselves against competition

The most influential way of protecting themselves was through the growth of patent life for drugs, as patents created a monopoly for pharmaceutical companies (Congress Watch, 2002). Vasallo & Sellanes (2002) referred to patent protection as the most serious adverse effect for consumers due to the limitation of new suppliers in the market. It was, paradoxically, protected by the government that had the power of issuing and enforcing anti-trust regulations and also the power to create these drug monopolies. This issue was critical for those new drugs aimed at terminal diseases as such as cancer. Common Cause (2001, p.13.) claimed: "Even though Bristol Myers Squibb and other companies have compassionate care programs to give these expensive life-saving drugs to some impoverished patients, critics claim that the high cost of these drugs has continued to pose terrible financial burdens on many cancer victims. There are people with second, third, and fourth mortgages on their houses to pay for this". Jeffrey Kraws, a pharmaceutical analyst for Gruntal & Co., told the Miami Herald "This isn't cough medicine. People are dying"(Common Cause, 2001, p.13.). These stories could be heard all over the world and fostered consumer prejudice against the pharmaceutical industry. This issue was contested by Holmer (2002) as he transferred the responsibility to the government as patients asked politicians "Am I still sick because there is no cure, or because my government has just said 'no new medicines for me'?" It was the eternal fight between the payers (government, HMOs) and the

pharmaceutical industry with each blaming each other for the imperfections of the health system as it was. Even then, patents were necessary for the pharmaceutical industry to be able to invest million of dollars in research and development to find new products.

The effective patent life of a drug in the USA averaged 13.9 to 15.4 years (National Institute for Health Care Management, 2000). Since the mid-1980s, the federal government has adopted a number of laws that extended the effective lives of drug patent by 4.4 to 5.9 years. The most significant laws, and the years they have added to the patent life of drugs, are below (Congress Watch, 2002):

- 1) The Hatch-Waxman Act of 1984 added, on average, 2.3 years to the patent life.

- 2) The prescription Drug User Fee Act of 1992 increased the efficiency of FDA drug review and approval and knocked 1.2 years off the review and approval process.

- 3) The Uruguay Round Agreements Act of 1994, an international trade agreement, added 1 year to the effective patent life.

- 4) The Food and Drug Modernisation Act of 1997 reduced the average number of years for clinical study by 1 year; FDAMA also gave six months of market exclusivity to a patented drug if a manufacturer tested the safety of the drug in children.

Those modifications were achieved due to lobbying by pharmaceutical companies (Common Cause, 2001), in order to protect their profits. It has been estimated that the Uruguay Round Agreements Act cost consumers more than \$6 billion due to delayed

access to generic drugs (Congress Watch, 2002) and a great part of this sum returned to the pharmaceutical industry.

Pharmaceutical companies lose billions from expiring patents when generics are introduced into the market. It has been estimated that the projected sales of drugs coming off patents between 2000 and 2004 were \$25.5 billion (Congress Watch, 2002). Claritin, a product of Schering Plough, received a lot of lobbying efforts to prolong its patent life. Claritin sold \$2.3 billion in 1999. Claritin's patent was extended two years by the Hatch-Waxman Act, 22 months under the Uruguay Round Agreements Act and six additional months because the manufacturer tested the safety of the drug for children (Congress Watch, 2002). Schering Plough pushed to extend its patent beyond 2002, basing its request on the fact that the approval of the antihistamine took an unusually long time, nearly 6 ½ years (Manning et al, 2001) compared to the normal 2.6 years. Schering Plough spent \$4.3 million on lobbying to achieve this objective but failed in the last session of Congress (Manning et al., 2001). Common Cause (2001, p.12) referred that "Consumer outrage and bad publicity over these patent extension attempts have so far stymied these congressional efforts". The Prime Institute of the College of Pharmacy (Manning et al, 2001) estimated that a three-year extension of the Claritin patent would have cost consumers more than \$5.3 billion.

Lobbying has had an effect on patent life growth in the USA by ensuring additional profits for brand-name products during their patent life. The result for the pharmaceutical industry of the six additional months of patent protection given for testing the safety of drugs for children represented additional profits of \$592 million per year (Congress Watch, 2002).

Preserve the freedom of establishing prices of products

Prescription prices rose at more than six times the rate of inflation in 2001 in the USA; the average price per prescription increased 10% while the rate of inflation was only 1.6% (National Institute for Health Care Management, 2002). This increase in prices was due to several factors (Congress Watch, 2002): more utilisation of popular drugs with above average prices, drugs aimed at seniors were far more expensive, and lack of price controls in the USA. Canada, the UK and Continental Europe did have price controls and patients paid between 35% and 50% less than the USA. These benefits in price freedom had been preserved by the industry so as to boost profits. USA sales, according to Public Citizen Congress Watch (2004), accounted for about 60% of global industry profits. In other words, Americans paid on average 60 cents of every \$1 that any pharmaceutical company in the world earned in profits.

Public Citizen Congress Watch (2002) stated that at the top of the industry's agenda was opposition to prescription drug coverage under Medicare and hostility to measures that would moderate rising drug prices. "Worried that the bulk buying power of Medicare would lead to discounted prices in the lucrative senior citizen market, the pharmaceutical industry launched an unprecedented blitz of lobbying, campaign contributions, and so-called issue ads to help its political allies and attack its enemies"(Congress Watch, 2001, p. I). The industry's political investments paid off as congress agreed to provide Medicare prescription drug coverage (Congress Watch, 2004) following the industry's interests. Republican leaders promoted the Medicare Reform bill that would encourage seniors to get drug coverage through private insurance companies and HMOs, preventing the states and the government from negotiating substantial price cuts (Congress Watch, 2004). Holmer (2004, p.2) confirmed that PhRMA highest priority was to focus all the lobbying resources on

“Enacting a high-quality Medicare drug benefit for seniors, delivered through the private sector”. This reform would have left prices unaltered but increased the demand for medicines as seniors got some kind of reimbursement. Public Citizen (2002) conducted studies in 13 states and major metropolitan areas that showed that the top 10 drugs used by seniors cost Medicare beneficiaries, who were without prescription drug insurance, nearly twice as much as pharmaceutical companies’ most favoured customers such as the Department of Veterans. It was also important to note that seniors represented 13% of the population but accounted for 34% of all prescriptions dispensed.

Tax breaks that improved the bottom line

Public Citizen Congress Watch (2002) referred to tax rates for the pharmaceutical industry that were much lower than other industries; the effective tax rate averaged 16% from 1993 through 1996 compared to 27% for all major industries over the same period. The pharmaceutical industry used tax credits to cut its taxes by almost \$28 billion between 1990 and 1996 (Public Citizen Congress Watch, 2002). The savings came from five federal tax provisions: the foreign tax credit, the possessions tax credit, the research and experimentation tax credit, the orphan drug tax credit and the expensing of research expenditures (Public Citizen Congress Watch, 2002). The research and experimentation tax credit, originally, enacted in 1981 as a temporary measure, had been extended 10 times, most recently in 2000 when Congress gave it a five year reprieve. The 20-percent credit rewarded research spending above a certain base level (Common Cause, 2001). The pharmaceutical industry had also taken advantage of a tax break for companies that built factories in Puerto Rico. From 1980 to 1990, the General Accounting Office (Public Citizen Congress Watch, 2002) estimated that 26 pharmaceutical companies enjoyed tax savings of \$10.1 billion thanks to the Puerto Rico facilities. There were several attempts to eliminate this particular tax break named Section 936. “The fight to

retain the section 936 credit consumed more lobbying and more political capital than all but the biggest ticket items in the proposed deficit reduction bill according to The Washington Post” (Common Cause, 2001, p.14.). In 1996 Congress did vote to eliminate this particular tax break but members did so following the drugs companies’ terms. The tax break did not apply to any future investments in Puerto Rico and current investments would have 10 years until the tax break was eliminated. That gradual phase-in represented a victory for the pharmaceutical lobby (Common Cause, 2001). Lobbying for tax breaks gave the pharmaceutical industry a sustained competitive advantage over other industries.

2.4.2:6 Economic impact of lobbying

Lobbying performed in Washington and in the regional legislation gave the pharmaceutical industry an extraordinary competitive advantage in the USA. According to the Fortune Magazine (Fortune Magazine, 2001) the pharmaceutical industry was the most profitable industry in America in year 2001. Fortune Magazine also stated that the 10 biggest US pharmaceutical companies saw their gross profits increase by 33% in 2001 in spite of the American economic slowdown. From the literature review, it could be concluded that pharmaceutical lobbying had been extremely effective during the last years in the USA. It is cited by Holmer (2002, p.1), CEO of PhRMA with its “and zero defeats in the United States Congress”, and also by consumer interest group Congress Watch (2002), that referred that the industry largely got what they wanted from politicians in Washington. In the corporatism/pluralism models, the pharmaceutical industry established a corporatist privileged relationship with congress, which permitted favourable legislation that improved the industry’s profit. In the literature there were some figures of how much a certain tax break or the extension of a patent life costs consumers but there had been no research analysing how much of the lobbying

performed by PhRMA, or by pharmaceutical companies, correlated to company sales, profits or market share. There were special cases such as the patent extension of Claritin where \$5.3 billion was estimated as the expected burden to consumers on the enacting of the extension of the patent life for 3 years (Manning et al, 2001). Also, the Medicare reform bill secured for drug makers \$200 billion in additional prescription spending (Congress Watch, 2004). There was no clear evidence in the literature whether those companies with in-house lobbyists had a better performance than those without.

There was also the consideration of Suranovic (2001) about the nature of lobbying and its distributive characteristic- transferring resources from consumers or from the government, in the case of tax breaks, to the pharmaceutical industry. There existed an opportunity cost because those resources could be used for the other needs of patients or society. This issue was one that the consumers or interest groups protested about. It could be concluded that consumers were being punished for the benefit of the pharmaceutical industry. The latter claimed that it needed these resources to research new products- that research was risky and that they needed high profits to fuel new research. However, evidence showed that the pharmaceutical industry had been very profitable for decades (Public Citizen Congress Watch, 2002), and therefore research cannot have been that risky. According to Fortune Magazine (2001) the top 500 pharmaceutical companies devoted 12.5% of their revenue to R&D compared to 18.5% profits and 30.4% to marketing and administration. Even then there was one key player missing in the analysis: the HMOs or Managed Care Organisations who actually paid for part of those medicines. There was also a distributive effect that transferred the resources of these organisations to the pharmaceutical industry. Those extra resources could have been used in improving the quality of health care or giving additional services to their affiliates.

Lobbying in Washington created additional value and an improvement of the economic environment for the pharmaceutical companies. Redwood (2002) argued that as industrial policy on pharmaceuticals was progressively abandoned in the European Union the focus of pharmaceuticals and biotech investment shifted towards the USA away from Europe. "The most visible symptom of this is the gradual emigration of new investment in activities and qualities that determine industrial competitiveness in the long run: research, development, advanced skills and an entrepreneurial approach to new ideas"(Redwood, 2002, p.7.). There have been many developments in this direction in the past years: Pharmacia (now owned by Pfizer) moved its corporate headquarters from the UK to the USA; Bayer moved its headquarters of its consumer medicines from Leverkusen to New Jersey; GSK after its merger moved its headquarters to the USA; Schering AG moved the management of its therapeutic division from Germany to New Jersey and Novartis was transferring its world-wide discovery and research activities to the USA (Redwood, 2002). What was noticeable is that these companies moved from countries- such as the UK, Germany and Switzerland- that were supposed to enjoy the best economic climate in Europe. In this case, although lobbying normally has a distributive effect, it created value for the American economy as it improved the economic environment by attracting industrial investments of foreign companies.

2.4.3 Lobbying of Managed care organisations

2.4.3:1 Managed Care Organisations

Pilnick, Dingwall and Starkey (2001) described *managed care* as a generic term for a variety of attempts to alter or restrict the treatment behaviours of health care professionals in order to produce both clinically effective and cost effective outcomes; at its simplest *managed care* is the management of medicines and treatment aimed at

containing costs and promoting effectiveness. Bengoa (1998) referred to managed care as a net of organisations that provide co-ordinated health services to a certain population and as accepting the responsibility of the clinical and economic outcomes of the health in this population. Although Bengoa cited this definition as managed care he meant a Health Management Organisation (HMO), which is an organisation or group of them that contracts and supplies medical care on the basis of a fixed periodic payment.

In the USA physicians were traditionally paid a fee per item of service; this created incentives for over-treatment and cost inflation and presented payers with an open-ended financial commitment (Pilnick et al., 2001). Managed Care Organisations (MCOs), the majority of which in the USA were either health maintenance organisations (HMOs) or preferred provider organisations (PPOs), changed these incentives by “eliminating fee for service in favour of delivery systems that encourage providers to control the costs” (Varney, 1995, p.1.) or by limiting the financial commitment of payers by paying clinicians a periodic fee for life covered (capitation) and making them share the risks of costs for excessive or expensive treatment. Employers, insurers, the state, or, more rarely, individual clients pay the Managed Care Organisations (MCOs). For the purpose of this research, MCOs are referred to as HMOs (Health Management Organisations) as these are the predominant type of MCO in Argentina.

In practice HMO organisational models vary considerably in detail and fee-for service providers have also adopted some features, such as the use of restricted drug formularies that blur the distinction between the various types (Pilnick et al, 2001). A formulary is a list of FDA-approved drug products by therapeutic category, along with relative cost information; these formularies were made available to pharmacies, physicians, third-party payers and or other persons involved in the health care industry in order to guide

in the prescribing and dispensing of pharmaceuticals. A restricted or closed formulary limits reimbursement to the specific drugs listed (Dranove, 2003). Pilnick, Dingwall & Starkey (2001, p.756.) pointed out “However, the HMOs’ economic incentives are usually reinforced by a range of direct interventions. These typically include controls on clinical autonomy, controls on patient choice and a degree of vertical integration. Controls on clinical autonomy include restricting the physicians’ choice of drugs to those included in a formulary or requiring disease treatment to follow specified protocols. Those controls were intended to change doctor’s prescribing behaviour in line with measures of efficacy and cost efficiency. They may be enforced either by individual case reviews or profiling, where doctors’ performance indicators are compared with a standard and deviations from it are investigated or sanctioned”. The principal objective of formularies was to bring down costs by selecting a narrower choice of drugs and adopting generics to replace the high-price brand-name products (Dranove, 2003). Motheral (2000) concluded that formularies can significantly reduce pharmaceutical utilisation in a non-continuously eligible population. However, this diminishing of costs is controversial as Redwood (1997, p.3.) described- “Cost containment pure-and-simple can be counter productive, as large-scale pioneering study of integrated health costs and outcomes has recently demonstrated. After analysing 240,000 prescriptions and 99,000 office visits by nearly 13,000 patients in six health HMO organisations across the US for one year, the study concluded that the most restrictive formularies had consistently caused the highest overall medical costs to HMOs and also caused patients greater inconvenience and longer periods of illness and discomfort”. Redwood made a point about the effectiveness of HMOs as the general focus was only on cost-containment of medicines and not on outcomes and overall costs especially, remarked Studin (2002), in those diseases as diabetes, congestive heart failure, asthma and depression where the system has pronounced deficiencies. But

Studin (2002) and Dranove (2003) noticed that the failure might lay not in the formularies but in the imperfections of the whole system of managed care such as lack of staff or capital in the HMOs to systematically adopt the practices of disease management or clinical-quality improvement, insufficient training of staff in such important areas as disease management, data analysis, patient and provider education and the poor relationship with the physicians which undermines the health plan credibility. HMOs could also benefit from collaborative activities with the pharmaceutical industry in order to measure the effectiveness of the disease management programs.

Pilnick et al, (2001) described another characteristic of managed care as restricting the providers to only consulting those employed by or holding contracts with the HMO in question. As a result of such restriction and standardisation, whereby patients relinquish some freedom of choice, HMOs could offer care more cheaply than traditional fee-for-service schemes.

The evolution of managed care practices looking for cost containment paved the way for the arrival of a new entity called Pharmacy Benefit Management (PBM). According to Dranove (2003), PBMs selected participating pharmacists, drug manufacturers, suppliers, administered point of sale claims processing systems, negotiated quantity discounts with pharmaceutical companies, administered plan record keeping and payment systems as well as maintaining quality control. PBMs also controlled costs by negotiating discounts from manufactures, usually in the form of rebates, in return for placing the manufacturer's drug on the PBM formulary. Consequently PBMs were intermediaries between the pharmaceutical industry, the HMOs and the pharmacies. PBMs were contracted by HMOs to handle their prescriptions and formularies. PBMs processed the information of prescriptions from their selected pharmacies and generated

information for the:

- Pharmaceutical company: In return for the inclusion of its products in a closed formulary, the pharmaceutical company paid the PBM a rebate related to the usage of its products by that HMO. In the model of Grossman and Helpman (1994), a contribution payment was paid to secure the company's product in a closed formulary.
- Health Management Organisations: The PBM, with the approval of the HMO, designed the formulary and provided the information to the HMO in return for a fee that could be fixed on a capitation or per-service basis. Controls could be implemented on protocols and adherence to the formulary.
- Pharmacies: PBMs paid pharmacies the amount equivalent to the reimbursements for patients.

2.4.3:2 Managed Care Account Managers

There was not a description of the activities of in-house lobbyists for obvious reasons - they were chosen on a one to one basis- but there were some descriptions of the activities that a *managed care account manager* of the pharmaceutical industry should perform regarding the relationship to the HMOs. The sources of this information were organisations that provided training for the pharmaceutical industry. Romar Consulting Associates (2002) referred to the *managed care account managers* as being responsible for building and maintaining strong positions for their companies in the HMO. For ASI Solutions (2002), another consulting company, the role of the managed care manager revolved around developing and managing contracts with HMOs. Romar added other activities such as conducting an account portfolio analysis, establishing objectives,

strategies, tactics and working with headquarter personnel to support strategic account plans. These definitions were vague and none of them permitted the clarification of the job description but they confirmed the existence of pharmaceutical managed care account managers who worked with the HMOs. Studin (2004) explained that manager account executives were hired to foster long-term relationships with managed care payers as pharmaceutical companies realised that the sales function could no longer just focus on physicians and hospitals but that selling had an institutional requirement on non-physician decision makers. Pharmaceutical managed care divisions were driven by their own contracting function, centred on the need to secure formulary positions. Collateral activities involved product pull-through. Standards for determining how pharmaceutical managed care divisions performed reverted to product sales.

2.4.3:3 Pharmaceutical industry and the introduction of products in formularies

“Health plans (HMOs) as a general rule distrust Pharma due to a perceived conflict of interest: financial support implies formulary positions are being sold, while partnerships compromise objective pharmacy and therapeutic (P&T) committee deliberations” (Studin, 2002, p.46.). There was certainly an influence by the managed care account executives on the inclusion of products in formularies although this was denied by the HMOs. Dranove (2003) concluded in his study that pharmaceutical companies whose representatives made more visits to the HMOS had a 77% higher chance to have their products included in the formulary. Some HMOs prohibited medical and pharmacy directors from having meetings with pharmaceutical account executives. Other national HMOs prohibited program, grant participation or another types of hospitality with pharmaceutical companies. Some HMOs stated that all dialogue with pharmaceutical companies had to be at a corporate level. A conflict of interest arose as the objectives of managed care organisations were opposite to the those of the managed care teams of the

pharmaceutical industry. The pharmaceutical company's objective was to maximise sales in a formulary and that of the HMO was to contain costs and provide a better service to their affiliates. But the true influence of pharmaceutical companies was at the PBM level where most formularies were done. In some exceptional cases the HMO contracted a PBM while preserving the right to decide which products were eligible for their formulary (Carroll, 2002) but most of the time the PBM decided about the formulary and the products included.

In the USA three PBMs- AdvancePCS, Medco Health Solutions and Express Scripts- covered 180 million people (Carroll, 2002), figures that showed a big concentration. Medco was owned by Merck Sharp & Dohme and it had one third of the PBM Market, a market estimated to cover 71% of the volume of outpatient medications covered by third-party payers (Lenzer, 2001). The Federal Trade Commission obliged Medco to create an independent Pharmacy and Therapeutics Committee aimed at deciding which products should be included in the Formulary. Merck Sharp & Dohme was also compelled to maintain a firewall between the two businesses with respect to other drug manufacturers' proposals, bids, contracts, discounts, etc. (Lenzer, 2001). Critics claimed that Merck's compliance with the consent decree was not perfect as it had its core products in the formularies of Medco (Lenzer, 2001).

Vertical integration was an effective way to secure positions in the formularies (Fons, 2002) but the other way in which the pharmaceutical industry influenced the design of formularies at the PBM level was through rebates. Those rebates represented contribution payments in the model of Grossman and Helpman (1994).

Carroll (2002) described two typical types of rebate offered to PBMs: the standard access rebate that gets a drug on the formulary and the market-share rebate. The market

share rebate was a special deal between pharmaceutical companies and the PBMs; an advantage in a therapeutic category may lead to a bigger market share in that category and result in an improvement in the bottom line and in stock prices.

Glabman (2004) explained that as PBMs were forced to cut pricing for handling prescriptions in order to compete for customers (HMOs), they implemented aggressive deals with pharmaceutical companies over rebates and discounts and had been requested, in return, to push more expensive branded medications. The Henry J. Kaiser Family Foundation conducted a study in year 2000 which concluded that saving through PBMs cannot be automatically ensured (Lenzer, 2001). Clients of the Merck-Medco PBM saw their prescription drug costs climb from \$18 billion in 1999 to \$23 billion in 2000. As some of these formularies were tied to a consumption rate the PBMs maintained their profits and the rebates and discounts were kept secret (Carroll, 2002). Halbert, CEO of Advance PCS, claimed that the bulk of the rebates and discounts were passed on to clients but Glabman (2004) stated that this was in fact not true as PBMs passed between only 5 and 8 percent onto reimbursement plans and received between 6 to 25 percent from pharmaceutical companies. The rebates should help to keep the costs low for HMOs and help the maximum utilisation of the drugs of the formulary. There was also secrecy regarding the different agreements between the PBMs and pharmaceutical companies. It was a common occurrence that representatives of the PBM urged physicians to use certain drugs, including branded medications. These agreements were paid separately under the terms of administrative fees or educational fees. States as Maine, South Dakota and Washington DC were litigating to obtain full disclosure of the rebate deals (Cross, 2005).

Critics claimed that the big money of the pharmaceutical companies was tied to the most expensive medications on the market (Glabman, 2004) and that PBMs pushed

higher-priced branded medications. Medco paid \$29.3 million to settle claims that it switched prescriptions to drugs that had increased costs for payers. Pharmaceutical companies also used a tactic called “bundling” in which the company conditioned its participation at the negotiation table with PBMs to the introduction onto the formularies of its high-priced name brands. The PBMs needed to complete the formulary with some of the products of this company, as well as the rebates, and so conceded to introduce the requested products. Bundling was also used for blocking competitors from being introduced onto the formulary. Duramed Pharmaceuticals (Carroll, 2002) sued and accused Wyeth of using bundling methods to block Duramed from a dozen different formularies. Hence, the inclusion of products in formularies was a controversial issue in the managed care setting. Although there should be an independent Pharmacy and Therapeutics Committee to decide which products were included in a formulary, with checks that none of the decision makers “inappropriately curry favour” (Studin, 2002, p.49.) with the pharmaceutical companies, the reality was that managed care account executives exerted influence in the inclusion decisions on HMOs or PBMs (Dranove, 2003) through rebates, special agreements or another means such as hospitality, grants or programs with key decision makers.

2.5 *Conclusions*

The formal macro-theory of lobbying described the different political theories of interest group participation in the political process and building the basis to the development of interest group formation theory. Within this framework, the theories of pluralism and corporatism provided the basis to understand how interest groups acted in a democracy. The pluralists (Dahl 1956) argued that power was spread throughout society with no sectional interest being dominant so that all interest groups were equal

in their access to influence political decisions. Several authors, Truman (1951), Polsby (1971), Cox (1988) Lindblom (1965) and Dahl (1991) added to this model.

On the other side, corporatism was developed by Schmitter (1974) as the extreme opposite to pluralism by looking to replace it. In corporatism, there were few interest groups that had privileged relationships with the state. Interest groups in corporatism were non-competitive, hierarchically ordered and recognised by the State. Lehmbruch (1977), Crouch (1983), Martin (1983) and Cawson (1985) extended the model. Both pluralism and corporatism, although different in their perspectives, stressed the important role of interest groups within the process of authoritative decision-making. The development of those two theories led to subdivisions such as the meso-corporatism (Wassenberg, 1982) and corporate pluralism (Kvavik and Heissler, 1974 and Kelso, 1978) aimed at introducing new functional perspectives in the original models.

Interest group theory was discussed based on the approach of Olson (1965) and extended by Salisbury (1969), Moe (1980), Kimber (1981) and Walker (1983). The critical views of Walker (1991), Maloney & Jordan (1997) and Rothenberg (1992) to Olson's approach were also explored. Salisbury's (1984) perspective that institutions were actors in the process of lobbying provided the understanding to include firms and corporations as actors in this process. Scholzman (1984), Moloney and Jordan (1996), Howell (2004), Kichner (1980), Coen (1997) and Woll (2006), confirmed this fact emphasising the importance of firms or corporations in the influence in decision-making circles.

The second section concentrated on the meso-theory of lobbying and presented the process of lobbying executed by interest groups from a game theory perspective. There

were two main channels of influence: the first one was that contribution payments influence the decisions of officials (Grossman & Helpman, 1994/1995, Rama & Tabellini, 1998, Mitra, 1999 and Damania & Fredriksson, 2000) deviating from maximisation of aggregate welfare. Interest groups looked to influence the decision-maker in order to benefit from the policy deviation; the second relied on the concept of asymmetric information (Potters & van Winden, 1992, Ainsworth, 1993, Austen-Smith & Wright, 1992/1998, Lohmann, 1993/1995 and Lagerlof, 1997). Politicians faced capacity constraints that gave them informational disadvantages compared to interest groups. Companies or groups of companies often possessed private information that was important for political decisions and, for instance, data about costs and demand or technological expertise that was valuable for the official to make the right decision. Interest groups transmitted information trying to influence the officials' decision. The Bennedsen and Feldmann (2001) model was also discussed as it was the only model that integrated both channels of influence, transmission of information and contribution payments.

The micro-theory discussed the characteristics of pharmaceutical lobbying in concrete situations. The American market was taken as a model, due to a lack of alternative literature, as it had the most similarities to the Argentine Market (Vasallo, 2002 and Vincent, 2003). The micro-theory of lobbying was divided in two parts: firstly, the lobbying carried out with congress officials and secondly the setting of HMOs and its instruments and the lobbying carried out with HMOs officials.

The lobbying of congress officials was performed by the companies themselves or by PhRMA, the chamber that represented the research companies (Public Citizen, 2001/2002). The pharmaceutical industry showed a privileged relationship to congress, fitting in as an interest group in the corporatism model. The pharmaceutical industry's

strategy focused on three issues: protect themselves against competitors through extension of patents, preserve price freedom and obtain advantageous tax breaks (Public Citizen, 2001). The achievements from this focus have successfully protected the bottom line of the pharmaceutical companies and made this industry one of the most profitable over the last decade.

The concept of managed care was explained and its elements such as Health Management Organisations (HMOs), Managed Care Organisations (MCOs), Pharmacy Benefits Management (PBM), closed formularies and rebates (Picknic et al, 2001, Motheral, 2000, Dranove, 2003). Managed care managers lobbied HMOs officials to secure formulary positions so that the companies' products achieved a larger share of the market (Studin, 2002).

Before addressing the research questions of 'why' and 'how' lobbying was carried out by the pharmaceutical industry, the researcher focused on the formal macro-theory of lobbying to be able to identify the characteristics of the pharmaceutical industry as a pressure group within the group formation theory. It was important to define whether the pharmaceutical industry fitted better on the corporatist or pluralist model to determine how it interacted with the government and officials. This type of interaction would determine how lobbying was carried out. The researcher could also identify, based on the macro-theory of lobbying, that the pharmaceutical industry was an interest/pressure group and that pharmaceutical companies and their pharmacopolitics managers were lobbying actors. This distinction was valuable to identify when the pharmaceutical industry was lobbying as a group on behalf of its members or an individual company, through its pharmacopolitics managers, was carrying out lobbying in pursuit of its individual interests. The formal theory was also explicit that different contexts would influence how lobbying was carried out and that lobbying style was

affected by the culture of where the lobbying was taking place.

The formal meso-theory of lobbying related to the research question 'how' lobbying was exerted. This theory provided two instruments of influencing the officials: contribution payments and transmission of information. The theory provided clear models of how those instruments were used. The researcher considered those instruments when he carried out the interviews and tried to define how they were used in lobbying in Argentina. The formal theory also stated that building of coalitions could prove useful when interest groups/lobbying actors joined to lobby the government. This related to the question of how lobbying was exerted whether by an individual company or a coalition. The theory also stated that companies would prefer to free-ride on others' lobbying efforts when they had a common interest so that they did not have to incur the costs of lobbying. The issue of free-riding related also to how lobbying was performed - free-riding meant that on certain occasions the individual company decided not to lobby.

The micro-theory of lobbying related to both research questions, 'why' and 'how', in concrete situations. The research question 'why' was answered as the literature review stated the key motivations for pharmaceutical companies as protection against competition, preserve the freedom of prices, obtain tax breaks and secure formulary positions. The research question 'how' was addressed and found a predominant attitude of companies towards carrying out a contribution payments strategy; in the case of lobbying congress, through contribution to political parties or lobbying through advocacy groups which contribute with politicians. In the case of HMOs, the contribution payments strategy was executed through the rebates offered to HMOs and PBMs to secure the company's products in the formularies. The researcher analysed the theory of lobbying from three different perspectives. The research questions of 'how'

and 'why' lobbying was carried out was explicit within these three perspectives. The researcher used the literature review to develop a fixed set of question for the interviews, which were the main source of data of this research.

In the next chapter the researcher discusses the methodology adopted for the research, namely grounded theory, and defines his position regarding the modernism and post-modernism movements and the paradigms of inquiry. The researcher also describes the different methodologies considered for this study and reviews the different phenomenological approaches to research. The researcher explains why he identified grounded theory as the most appropriate methodology for this study and describes how grounded theory was used in the research process.

CHAPTER 3: *METHODOLOGY: GROUNDED THEORY*

3.1 *Methodology*

For this study the researcher followed the Strauss & Corbin (1998) model of *grounded theory*. The researcher's philosophical attitude was post-modernist and had the aim of interpreting and reflecting over the data gathered in the interviews. The researcher aimed to provide a better understanding of the research object: pharmaceutical lobbying. This understanding was limited by the subjective interpretation of the researcher. The methodological approach adopted was phenomenological which led to an inductive-deductive interpretation of the data in the open coding stage and later, through the axial coding, comparison making and sub-category building. This inductive-deductive process was a characteristic of *grounded theory*, in which the researcher "makes comparisons and secondly asks questions" (Howell, 2000, p.129). Regarding the paradigms of inquiry the researcher opted for the classification of Guba and Lincoln (2001) that identified two paradigms of inquiry that fitted in with the research: post-positivism and constructivism. The researcher was part of what was investigated and there cannot be separation between the investigator and the research object. Reality was locally constructed and was based on the experiences of the researcher and the interviewees. The results were constructions of the researcher based on his reflections of the data collected.

3.2 *Issues of methodological choice*

3.2.1 *Modernism and Post-Modernism*

Modern models of inquiry were developed in movements that originated in the

philosophy, literature and culture of the last two centuries. Modernism was characterised as looking for the new, the rationalism of the mind and a scientific method by which to explain an external reality. Postmodernism was largely a reaction to the assumed certainty of scientific or objective efforts to explain reality. In essence, it stemmed from recognition that reality was not simply a mirror of human understanding of it but, rather, was constructed as the mind tried to understand its own particular and personal reality (Kelly, 1997). When Nietzsche, in the nineteenth century, said there were no facts only interpretations he was both summing up the legacy of eighteenth-century critical philosophy and pointing towards the tasks and promises of the twentieth-century post-modernism movement (Tarnas, 1993). For this reason postmodernism was highly sceptical of explanations which claimed to be valid for all groups, cultures, traditions and races but instead focused on the relative truth for each person (Kelly, 1997). For the post-modernist, interpretation was everything; reality only came into being through individual interpretation of what the world meant to us as individuals. Postmodernism relied on concrete experience over abstract principles, knowing always that the outcome of one's own experience will necessarily be fallible and relative, rather than certain and universal (Tarnas, 1993).

In philosophy and epistemology, this change from modernism to post-modernism took place in a dramatic series of intellectual advances that began with Descartes and culminated in Kant (Field, 2001). It has been argued that Descartes (1637) and Kant were both essential in the development of the modern perspective. It was Descartes (1637) who first fully grasped and articulated the experience of the emerging autonomous modern self as fundamentally distinct and separate from an objective external world that it sought to understand. Descartes (1637) drew out and expressed in philosophical terms the experiential consequence of the new Copernican cosmological

context, starting from a position of fundamental doubt vis-à-vis the world and ending in the *cogito* (Tarnas, 1993) in which he asserted thinking was the first item of knowledge. In doing this he set into motion a train of philosophical events- leading from Locke to Berkeley and Hume (Field, 2001) and culminating in Kant- that eventually produced a great epistemological crisis. Descartes was in this sense the crucial midpoint between the Copernican revolution in cosmology and the Kantian revolution in epistemology.

Tarnas (1993) stated that Kant, built on his empiricist predecessors, drew out the epistemological consequences of the Cartesian *cogito*. Of course, Kant himself set forth cognitive principles and subjective structures that he thought were absolute e.g., forms and categories on which were based the apparent certainties of Newtonian physics (Brown, 2001). As time passed, however, Kant's legacy was not the specifics of his solution but rather the profound problems he articulated. Instead, Kant had drawn attention to the crucial fact that all human knowledge was interpretive. Field (2001) added that the human mind can claim no direct mirror like knowledge of the objective world, for the object it experiences has already been structured by the subject's own internal organisation. The human being knows not the world-in-itself but rather the world-as-rendered-by-the-human-mind. Thus Descartes ontological schism was both made more absolute and superseded by Kant's epistemological schism. The gap between subject and object could not be certifiably bridged. From the Cartesian premise came the Kantian result. (Tarnas, 1993).

The cosmological estrangement of modern consciousness initiated by Copernicus and the ontological estrangement initiated by Descartes were completed by the epistemological estrangement initiated by Kant: a threefold mutually enforced prison of modern alienation. And with the third of this trinity of modern alienation, the great

schism established by Kant, we see the pivot of the shift from the modern to the post-modern.

3.2.2 Paradigms of Inquiry

It was important to define a paradigm. Recalling the Greek paradeigma would remind us that paradigm was derived from model, pattern and example (Trafford, 2001). Kuhn (1962, p.10) suggested that scientific paradigms were “Accepted examples of actual scientific practice, examples which include law, theory, application and instrumentation together.... (to) provide models from which spring particular coherent traditions of scientific research”. According to Kuhn (1962), paradigms were also the source of the methods, problem-fields and standards of solution accepted by any mature scientific field at any given time. Kuhn (1962) pointed out that each paradigm tended to create its own data and its own way of interpreting those data in a manner that was comprehensive and self-validating. Barker (1992) took the notion of the Kuhnian paradigm and applied it to everyday issues. By his definition a paradigm was a set of rules and regulations (written or unwritten) that did two things: 1) established or defined boundaries; and 2) indicated how to behave inside the boundaries in order to be successful. His reason for aligning paradigms with notions of success was on the basis that if individuals found that operating within a prevailing orthodoxy inhibited their achievement of success, then they would seek ways to overcome that problem. When a new way of working was discovered, it would replace the previous paradigm.

Hussey and Hussey (1997) identified two main research paradigms: positivism and phenomenology. Hussey and Hussey (1997, p.52) explained that “Positivist laws provide the basis of explanation, permitting the anticipation of phenomena, predict the occurrence and therefore allow them to be controlled”. Explanation consisted of

establishing causal relationships between the variables and linking them in a deductive or integrated theory. This approach related to the natural sciences where the scientific method was modelled on controlled experiments aimed at the development of a general theory. But social sciences could not be regarded as being bound by certain fixed laws in the sequence of cause and effect. The phenomenology paradigm argued that social sciences cannot be compared to physical sciences and social reality was within the human mind. This paradigm stressed the subjective aspects of human activity by focusing on the meaning rather than the measurement of social phenomena (Hussey and Hussey, 1997). Researchers sought to understand the nature of society through personal experience and gain insight into social phenomena from the perceptions and values of respondents as well as analysing the meaning of certain social actions. The typology enunciated by Hussey and Hussey established the two main research paradigms; other authors have made a more specific classification which could better help the researcher to link his or her paradigms of research and research methodology.

Guba and Lincoln (2001) analysed the issue further and identified a number of different paradigms of inquiry. These involved positivism, post-positivism, critical theory, constructivism and participatory. Positivism and post-positivism entailed aspects of modernism while the others identified different gradients of post-modernism.

Table 4 *Modernism/ Postmodernism and Paradigms*

| Modernism (1860-1960) | | Post- Modernism (1960-2005) | | |
|-----------------------|-----------------|-----------------------------|----------------|---------------|
| Positivism | Post-Positivism | Critical Theory | Constructivism | Participatory |

Positivism: Positivism was identified by Comte and St. Simon, during the mid 19th Century, and they tried to copy the methodological approaches followed by the natural sciences. It was normative and descriptive: it described how human thought had evolved and prescribed the norms of how it should develop (Howell, 2004). Positivism considered that an external reality existed, which could be discovered and totally understood. If the investigator and the external world (or that which could be discovered) were totally separate and objectivity sought through scientific procedure, truth could be found (epistemology) (Guba and Lincoln, 2001). Trafford (2001) stated that this could be achieved by tests and attempting to prove hypotheses, through scientific experiments and the manipulation of confounding conditions (methodology). This paradigm allowed a distinct understanding of theory in that theory provided immutable laws, which enabled prediction. It is difficult or almost impossible to find immutable laws and prediction in social sciences and thus this paradigm was heavily criticised by post-positivists, who argued that truth exists but can only be understood imperfectly. Positivists claimed that science should establish laws that were beyond challenge. This undermined the critical aspect of positivism and in many instances began to hold up scientific discovery. If laws could not be challenged then progress was restrained. Indeed, positivism omitted and alienated many approaches to generating knowledge and was eventually challenged by post-positivism.

Post-Positivism: Post-positivism perceived reality as external to humanity but considered that through our intellectual capabilities we are unable to understand the real world. Epistemologically speaking, post-positivism abandoned the total separation between the investigated and investigator. However, objectivity and separation were still pursued. This led to a methodology that dealt with multiple scientific experimentation and hypothesis falsification (Howell, 2004). Theory was about

approximations to the truth. Popper was the main representative of this paradigm. Popper argued that instead of constantly seeking proof, researchers should rather seek evidence that might refute a hypothesis or theory (Trafford, 2001). He argued that if a theory was developed from empirical evidence then it should also be possible to refute that theory from a base of relevant and contradictory evidence. The more tests for falsification a theory passed, the more it gained in corroboration. Theories that withstood refutation tests without being falsified were seen as corroborated hypothesis and were held to be provisionally true as the best available theory. Popper's critics insisted that corroboration is a form of induction. Popper was blamed for internal inconsistencies insofar as his methodology relied on implicit and unrecognized elements of induction and for paralyzing rationalism insofar as rationality demanded justification of some sort.

Critical Theory: Post-positivism generated problems for those social scientists who sought to identify and challenge what was taking place in institutions from historical and mainly qualitative perspectives. This led to the emergence of *critical theory* (Howell, 2004). The epistemological aspect of the critical theory paradigm considered that findings and theoretical perspectives were discovered because the investigator and investigated were intrinsically linked through historical values, which must influence the inquiry. A specific understanding of reality was shaped by social, political, cultural, economic and gender values and crystallised over time. This led to a specific methodology which identified a dialogic and dialectical approach (Guba & Lincoln, 2001). Dialogue was needed between the researcher and the subject and between past and present. Theory was developed subjectively in a historical context.

Constructivism: Constructivism understood reality as locally constructed and based on shared experiences even though groups and individuals are changeable; ontologically,

this identifies *relativist realism*” (Howell, 2004). Epistemologically, constructivism was similar to critical theory except that it considered that findings were created and developed as the investigation progressed. This meant that results were created through consensus and individual constructions, including the constructions of the investigator. Theory in this paradigm was relative and changeable, reliability and prediction almost impossible, and cause and effect difficult to identify (Guba & Lincoln, 2001).

Participatory: This paradigm ontology perceived reality as participative with an interaction between subjective and objective perspectives. Indeed, reality was co-created through mind and cosmos or external world (Guba & Lincoln, 2001). The epistemology involved critical subjectivity of the self in participatory transactions with the cosmos or other. Findings were co-created through practitioner attributes such as experience and practical knowledge. The methodology in this paradigm of inquiry involved collaborative action and political participation through the primacy of practice and language grounded in shared experience and situational context.

The following chart differentiates between the ontology, epistemology and methodology of the five paradigms. Trafford (2001) stated that ontology was concerned with the very essence of the phenomena under investigation. The question that the researcher was expected to consider was whether reality was external to the individual or was it the product of human consciousness. An associated question was whether reality was objective or the product of human cognition. Epistemology was concerned with the very basis of knowledge. The question that the researcher was expected to consider was whether knowledge was true or false, hard, real and transferable or soft, subjective and only found in personal experience (Trafford, 2001). Methodology was concerned with the ways that the investigation was conducted to obtain evidence from, and about, the social world. Here, the researcher had to be clear whether his/her

research was concerned with searching for universal laws that explained and governed the nature of society, or whether it concerned understanding the way in which individuals created, modified and interpreted the world in which they found themselves.

Table 5 *Guba & Lincoln Basic beliefs of Alternative Inquiry Paradigms(2001)*

| Issue | Positivism | Post-positivism | Critical Theory | Constructivism | Participatory |
|---------------------|--|--|--|---|--|
| Ontology | Naïve realism – “real” reality but apprehend able | Critical realism – “real” reality but only imperfectly and probabilistically apprehend able | Historical realism- virtual shaped by social, political, cultural, economic, ethnic and gender values crystallized over time | Relativism-local and specific constructed realities | Participative reality- subjective-objective reality, co-created by mind and given cosmos |
| Epistemology | Dualist/ objectivist; findings true | Modified dualist/ objectivist; critical tradition/ community; findings probably true | Transactional/ subjectivist; value-mediated findings | Transactional/ subjectivist; created findings | Critical subjectivity in participatory transaction with cosmos; extended epistemology of experiential, propositional, and practical knowing; co-created findings |
| Methodology | Experimental/ manipulative; verification of hypotheses; chiefly quantitative methods | Modified experimental/ manipulative; critical multiplism; falsification of hypotheses; may include qualitative methods | Dialogic/ dialectic | Hermeneutic/ dialectic | Political participation in collaborative action inquiry; primacy of the practical; use of language grounded in shared experiential context |

Hussey and Hussey (1997) maintained that paradigms were widely used to differentiate the ontological, epistemological and methodology issues in research. Guba & Lincoln's (2001) positivism and post-positivism paradigms corresponded to Hussey and Hussey's (1997) positivism. The paradigms constructivism, critical theory and participatory corresponded to Hussey and Hussey's phenomenology paradigm.

3.2.3 Methodologies for research

The research methodologies used were determined by the paradigm chosen, or assumed, by the researcher. There were two different types of research methodologies: positivistic methodologies (cross-sectional studies, experimental studies, longitudinal studies and surveys) and phenomenological methodologies (Hussey & Hussey 1997). For the purpose of the study the focus was on phenomenological methodologies. Phenomenology itself was regarded as a paradigm of inquiry but has also been identified as a methodology of research by some authors.

Phenomenology: Husserl is acknowledged as the founding father of phenomenology as a systematic study of social behaviour and its evolution can be traced from the work of Kierkegaard and Nietzsche. Husserl developed a phenomenological methodology as a descriptive procedure for examining conscious experience that was called descriptive phenomenology (Natsan, 1973). Heidegger developed hermeneutic (interpretive) phenomenology, or existential phenomenology, pointing out that the basic problem of philosophy was to discover the nature of being (Goulding, 1999). Schutz, during the 1960s, combined Husserl's phenomenology with a social phenomenology and called for the use of bracketing. This implied setting aside one's taken-for-granted assumptions in order to focus on the ways in which members of the real world interpretively produce the recognisable, intelligible forms they treat as real (Goulding, 1999). Merleau-Ponty

(1962) expressed a similar point of view and understood phenomenology as the study of essences and that all problems amounted to finding definitions to the essence of consciousness or perceptions. Thompson et al. (1990) discussed the application of phenomenology to the research process. The basic assumption was that a person's life was a socially constructed totality in which experiences interrelate coherently and meaningfully. The researcher found that phenomenology as a methodology was of limited use in this study because of a need to limit his reflections to his own conscious mental process and lived experiences. Consequently reflection would be carried away by a unavoidable subjectivity.

Action Research: Action research differed from phenomenology as the researcher's objective, in action research, was not to interpret but to bring change to the research object. Action research was closely linked to participative inquiry and was designed to find an effective way of bringing about a conscious change in a partly controlled environment. In other words, the main aim of action research was to enter a situation and to attempt to bring about change and monitor the results. Some action research might not be different from a consultancy project (Hussey and Hussey, 1997). Gummesson (2000) suggested that a program of several research projects and researchers provided a better opportunity to combine the roles of academic researcher and management consultant. In this light, the interrelationship between the researcher and consultant roles occurred over time as well as between different researchers within the framework of a larger program. . For the purpose of this study the researcher took an exploratory approach with the aim of having a deep understanding of the pharmaceutical lobbying process. Therefore, action research was not appropriate as the researcher did not wish to bring about any changes to the research setting.

Ethnography: Ethnography was based on anthropology and was an approach in which

the researcher used socially acquired and shared knowledge to understand the observed patterns of human activity (Atkinson & Hammersley, 1998). The main method was participatory observation in which the researcher became a full working member of the group being studied. It normally took place over a long period and in a clearly defined location. As such, ethnographic research was essentially phenomenological in nature and was not replicable (Trafford, 2001). Ethnographers sought to capture and then to understand the detailed aspects of their subject's life-activities. This type of research involved building trust, becoming involved with the phenomenon researched, developing strong contacts with the key informants, gathering data from multiple sources, writing notes and trying to be analytical of the whole process. Ethnographers have to balance the consequences of close contact against professional detachment towards their subjects (Atkinson & Hammersley, 1998). Although the researcher was immersed in his own culture, and ethnography as a methodology was a possibility, the researcher broadened the scope of research to the whole pharmaceutical industry in Argentina and thus other methodologies were more suitable.

Case Study: The case study methodology was developed by Eisenhardt (1989) and Yin (1994). Eisenhardt (1989, p.534.) referred to the case study as “a research study which focuses on understanding the dynamics present within single settings”. A case study was the examination of a single phenomenon. Yin (1994) organised and standardised the case study research methodology. Yin's (1994) purpose was to give reliability and validity to the case study research within academic opinion. Yin (1994) broadened Eisenhardt's (1989) approach from the single case study research to a multiple case study research, whose objective was to find patterns across similar cases, constructing an emergent theory. Yin's (1994) aim was to reach saturation of the findings across the cases. He defined this saturation as literal replication. However, Yin's (1994)

methodology was aimed not only at literal replication but also at theoretical replication. Theoretical replication meant that the emergent theory was confronted with a study of non-similar cases which should show non-correspondence to the findings obtained in the literal replication. Theoretical replication made the findings construct more valid. In case study research, multiple sources could be considered, either qualitatively or quantitatively. Case studies were often described as exploratory research and were used in areas where there were few theories or a deficient body of knowledge. At first the researcher considered case study methodology to be appropriate for the study. On reflection he realised that an *a priori* conceptual framework and predetermined propositions could introduce more bias in the interview process and so decided to follow a more inductive methodology.

Grounded Theory: Glaser and Strauss first proposed *grounded theory* in 1967 in their book “The discovery of Grounded Theory” (Glaser & Strauss, 1967). Glaser’s definition of *grounded theory* was “a general methodology of analysis linked with data collection that uses a systematically applied set of methods to generate an inductive theory about a substantive area” (Glaser, 1992, p.16). Grounded theory emphasised the systematic approach to data collection, handling and analysis and was aimed at building a substantive theory that explains the area under investigation. Glaser’s and Strauss’s personal differences that emerged over the years following their joint publication in 1967 saw Glaser (1992) emphasising the necessity for the researcher to be more creative and less procedural in methodology. Glaser’s approach was more inductive and followed the constructivism paradigm. Strauss (Strauss & Corbin, 1990), conversely, conveyed a more linear method. The latter approach could be considered to be within the post-positivism/constructivism paradigms of inquiry. Glaser (1992) selected an area (or organisation or activity) for study and allowed issues to emerge in the course of the

research process. Strauss and Corbin (1990) were more specific and preferred to identify a phenomenon or issue for study. Thus Glaser's (1992) approach, to the identification and specification of the research issue to be addressed, was entirely dependent upon the perceptions of actors and researcher. Strauss and Corbin (1998) permitted the researcher to predetermine the general subject of enquiry before entering the research site. Glaser (1992) also preferred an analytical method that was more general in its frame of reference, while Strauss and Corbin (1998) opted for a somewhat more structured set of analytical steps. Glaser (1992) regarded Strauss and Corbin's analytical method as forcing, rather than allowing emergence of theory. In this respect Glaser's methodological approach relied primarily upon the constant comparison of different incidents, perceptions, relationships and issues. Glaser's aim was to identify inconsistencies, contradictions, gaps in data and emerging consensus on key concepts and relationships- "in grounded theory we do not know, until it emerges" (Glaser, 1992, p.95). Strauss and Corbin (1998) were significantly more prescriptive in specifying the steps to be taken by a researcher in coding and analysing phenomena.

In essence, the process of grounded theory required that joint collection, coding and analysis of data were the underlying operations. "The generation of theory, coupled with the notion of theory as process...should blur and intertwine continually, from the beginning of an investigation to its end" (Glaser and Strauss, 1967, p.43). In grounded theory the methodological emphasis was on actors' own emergent interpretations and meanings with minimal researcher intervention. The theory that was grounded in these data emerges through constant comparison, coding and analysis of interview and observational data. Van Maanen (1979) stated that what was pertinent to social research, through grounded theory was that it sought to approximate to the context of that being studied, for example: an organisation, its managers and the interactions and

interrelationships between them, thus conveying a conceptual understanding of issues that make up their world (Van Maanen, 1979). The main problem that the researcher found with grounded theory was the issue of bias and subjectivity of the findings as the researcher was himself coding and interpreting the relationships between the different concepts, sub-concepts, properties and conditions.

3.2.4 Ontological, epistemological, and methodological assumptions related to inquiry paradigms

An investigator's assumptions and beliefs about society influence his/her choices regarding the research methodologies. He may use a deductive methodology that requires starting with general ideas and developing a theory with testable hypotheses, which can be tested by data collection. Alternatively, he may prefer to use an inductive approach, which begins with observations and builds up ideas and more general statements and testable hypotheses or propositions from them for further testing based on additional observations. These two approaches can be defined or categorised as positivism and phenomenology. Creswell (1994) defined positivist or quantitative approaches as based on testing a theory composed of variables, measured with numbers, and analysed with statistical procedures, in order to determine whether the predictive generalisations of the theory. Easterby-Smith et al made assumptions of independence:

“The observer is independent of what is being observed; value-freedom: the choice of what to study, and how to study it, can be determined by objective criteria rather than by human beliefs and interests;[and] causality: the aim of social sciences should be to identify causal explanations and fundamental laws that explain regularities in human social behaviour” (Easterby-Smith et al, 1991, p.28.).

The range of approaches, which were summarised as qualitative, in contrast, assert that

“Many subjects of interest to social scientists cannot be meaningful formulations in ways that permit statistical testing of hypotheses with quantitative data” (Trafford, 2001, p.20). Qualitative or phenomenological research aims to develop understanding of social or human problems through a process which is based on building a complex, holistic picture, formed with words, reporting detailed view of informants (Creswell, 1994). Such an approach was held to be more useful for hearing data and understanding meaning in context, than positivism, which denied the significance of context and standardises questions and answers (Rubin and Rubin 1995). The general perspective of the researcher in this study was phenomenology. The phenomenological paradigm fitted the research as it was concerned with generating theory from small samples where the data was rich and subjective. However, the researcher found that the classification of Guba & Lincoln was more appropriate for the research. Considering the paradigm of inquiry related to the Guba & Lincoln (2001) classification, the researcher opted for a post-positivist and constructivist approach. The ontological assumption of this research was that reality was imperfectly apprehendable, relative, local and specifically constructed. The epistemological assumption was that findings arose from the interaction of the researcher with that being researched. The methodological assumption was aimed at understanding the way in which pharmaceutical lobbying was exerted through an inductive-deductive process. The black boxes in the following table show the researcher’s approach to the research object.

Table 6 *Researcher’s approach to the research object*

| | | | | | |
|------------------------------------|------------|-------------------|--------------------|------------------|---------------|
| Movements | Modernism | | Post-Modernism ■ | | |
| Research Methodological Approaches | Positivism | | Phenomenological ■ | | |
| Paradigms | Positivist | Post-Positivist ■ | Critical Theory | Constructivism ■ | Participatory |

The researcher's philosophical attitude was post-modernist, with a phenomenological research approach and the paradigm of inquiry was post-positivist and constructivist.. This mixed approach of the paradigms of inquiry led to the adoption of grounded theory as the methodology used. The researcher followed the model of Strauss and Corbin (1998), which made the approach more post-positivistic following certain procedure in the development of the substantive theory. If the researcher had followed Glaser's (1992) approach the paradigm of inquiry would have been only constructivist.

3.3 The research questions

The research addressed the question of how multinational pharmaceutical companies in Argentina lobby the government, public and HMO officials by using pharmacopolitics managers and departments. The research also looked at the expected outcomes and motivations of the pharmacopolitics activities. In order to accomplish the aims of this study, the following research questions were used:

Why do multinational pharmaceutical companies in Argentina lobby officials?

How do multinational pharmaceutical companies carry out lobbying activities?

These research questions were exploratory and they were aimed at understanding the pharmaceutical lobbying process in Argentina.

3.4 The research domain

The study was placed within the context of the multinational pharmaceutical industry in Argentina where the function of pharmacopolitics is clearly outlined in company hierarchy. A pharmacopolitics manager's job is to lobby the government and influence HMO officials. National companies also undertake lobbying but as there was not

usually a clear job description covering this responsibility within the organisation it was difficult to research. It was also very difficult for the researcher to gain access to national companies.

3.5 *Deciding on research methodology*

The formal meso-theory of lobbying was mostly based on the game theory; formulating mathematical models with contribution payments or information communication. Initially the idea was to develop a quantitative Bayesian approach, which changed gradually to one that tallied with the game theory. However, after reading Miles and Huberman (1994) the researcher realised that he was taking an analytic approach to understand a few controlled variables and for a deeper understanding of the interaction of variables in a complex environment a systemic approach was needed. Consequently the approach turned out to be phenomenological with the aim of developing a deep understanding of the process of lobbying by multinationals in Argentina. The researcher analysed the different possible methodologies available. Action research was disregarded because the aim of the research was not to solve a particular problem but to develop theory about a phenomenon. Ethnography was considered but the researcher's interest was to understand pharmaceutical lobbying not only from the perspective of his own organisation but also from the multinational industry. After disregarding other methodologies (phenomenology, participative inquiry) the researcher realised that the two methodologies that best fitted the research process were *case study research* and *grounded theory*. The researcher first opted for a *case study research* looking for literal and theoretical replication across the cases. However, later, the researcher decided to use *grounded theory* as a methodology due to the distinctive advantages that it commenced from specific 'grounded in reality' situation (a pharmaceutical company) with the intent of understanding the nature and rationale of observed incidents.

Inductive theory generation was embedded in the explanation of pharmaceutical lobbying, rather than generalities or broad statements. The explanatory power of grounded theory was to develop predictive ability - to explain what happens in the context of pharmaceutical lobbying. Grounded theory was considered to be particularly appropriate when little was known about a topic and there were few existing theories to explain a particular phenomenon (Hutchinson, 1988) as happened with pharmaceutical lobbying in Argentina.

By choosing *grounded theory* the implication was that the conceptual framework would be developed after the coding and analysis; no theoretical framework was to be developed *a priori*. The theoretical framework was to be developed by alternating between inductive and deductive thought. The researcher inductively gained information that was apparent in the data collected. Next, deductive thought allowed the researcher to turn away from the data and establish the relationships between the sub-categories. Substantive theory emerged from the analysis of data through the relationships between sub-categories, properties and concepts.

3.5.1 Grounded Theory: Glaser or Strauss?

The first decision was to decide between the different approaches in using grounded theory. As noted in the literature review Glaser and Strauss (1967) disagreed on the rationale/basis of how Grounded Theory should be implemented. Glaser (1992) followed a more constructivist approach and Strauss and Corbin (1990) a more post-positivistic approach. The researcher opted for the Strauss and Corbin (1998) approach because this permitted a predetermination of the general subject of enquiry before entering the research site and allowed the adoption of a structured set of analytical steps

to be taken in coding and analysing phenomena. Nevertheless, some elements of Glaser's (1992) approach, such as theoretical sensitivity, were used.

By following the Strauss and Corbin (1998) approach the researcher elected in advance to focus observation, interviews and archival data gathering on a particular issue such as lobbying by the pharmaceutical industry. Coding was then oriented around this issue and a central concept sought to represent the interplay of subjects' and the researcher's perceptions of the nature and dimensions of the issue being studied. The generation of grounded theory involved data being systematically collected through field observations, interviews, meetings and the inspection of documentation where possible. In the field of pharmaceutical lobbying, due to the sensitivity of the topic, written documentation was scarce or non-existent. The only written documentation that the researcher could collect was the output i.e. legislation achieved through lobbying. The researcher, as a participant observer, could notice first the lobbying implemented by the pharmaceutical companies aimed at a specific interest and later saw the outputs of this lobbying activities.

Grounded theory aims to build substantive theory through coding data. The intention was to develop core categories that accounted for most of the variance by closely scrutinising the data. The aim of coding was to arrive at systematically derived core categories that become the focal concepts that contribute towards theoretical development. Theory generation was established within seven sub-categories and one core category. Categories were coded with a view to rendering them 'dense' and 'saturated' with theoretical meaning.

3.6 Theoretical Sensitivity

Theoretical sensitivity refers to the researcher's capacity to reflect on the data in theoretical terms. It required the researcher to interact continually with the data collection and analysis and reflect on the data while suspending judgement on possible outcomes. The researcher came to the research situation with a high degree of sensitivity as he worked as a pharmapolitics manager and had experience relevant to the area. The researcher had to be aware during the whole research process of the impact that his "self" could have in the outcomes of the study. The researcher's subjectivity and sensitivity might have influenced how the researcher conducted the interviews, analysed and interpreted the data. The researcher used the iterative and grounded processes of the constant comparison methodology to counteract, or at least diminish, subjectivity and bias. Reflexivity and the bias effect are dealt with further in this chapter.

3.7 Coding

Coding is the result of raising questions and giving provisional answers about categories and their relationship. Creating distinctions between codes produces dimensions and sub-dimensions. The researcher applied the coding paradigm originally articulated by Strauss (1987) and further refined by Strauss and Corbin (1990). It represented the operations by which data was broken down, conceptualised, and put back together in new ways (Strauss and Corbin, 1998). Strauss and Corbin identified three types of coding: open coding, axial coding and selective coding. Through coding the researcher labelled fragments of data through the various developmental stages.

3.7.1 Open Coding

Open coding involved the analysis of data gathered in the interviews, by participant

observation and to a lesser degree by archival information. Codes formed the basis for later aggregation into concepts. These were names, or labels, that the researcher gave to events, activities, functions, relationships, contexts, influences and outcomes. This initial coding involved close scrutiny of the data from the first interviews. The researcher transcribed and then analysed interviews, word for word, line-by-line and phrase-by-phrase. The aim of open coding was to begin the unrestricted labelling of all data and to assign representational and conceptual codes to each and every incident highlighted within the data. As the process moved forward then iterative reflection of that already coded was considered with the new data so that a gradual formation took place. Open coding allowed similar incidents and phenomena to be compared and contrasted. This initiated the tentative process of developing conceptual categories and their properties. The researcher bore in mind that it was not the data itself that developed conceptual categories and their properties but subsequent reflection on the data that built the emergent substantive theory. It was the theorisation of data and their phenomena, through an inductive-deductive process, that created grounded theory. The theory was literally grounded in the data, but was not the data itself.

3.7.2 Axial Coding

Axial coding followed open coding. After completing the initial open coding the researcher then regrouped the data. Through axial coding the researcher identified relationships between concepts, properties, dimensions, phenomenon and intervening conditions for the purpose of developing categories. Sub-categories emerged as aggregates of the most closely interrelated elements for which supporting evidence was strong (Strauss and Corbin, 1998). Initially the researcher identified 10 sub-categories, 28 concepts and 30 sub-concepts. Through the process of refining the categories and delving into the data the researcher identified four new sub-categories. It was during this

process of moving from the transcript of one respondent to that of another, and on towards the final categories, that tentative relationships emerged. Finally, the 15 sub-categories were merged into seven sub-categories. Axial coding is extensively described in the data analysis chapter.

3.7.3 Selective Coding

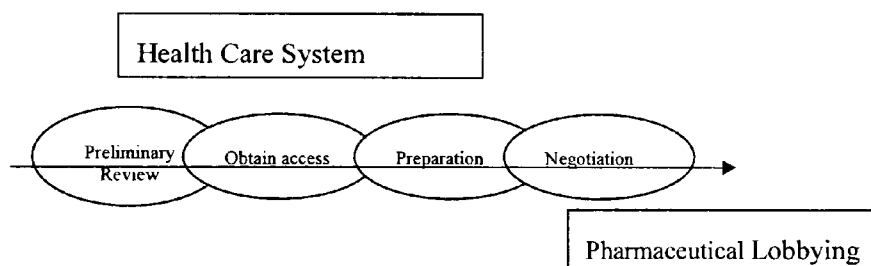
“Selective coding is the process by which all categories are unified around a core category” (Strauss & Corbin, 1990, p.15). Selective coding required the selection of the focal core code, the central phenomenon that emerges from the axial coding process. The focal core code for this research was **pharmaceutical lobbying**. All the other seven sub-categories derived from the axial coding process were related in some way to this focal core code. The researcher classified these sub-categories as representing context, conditions, actions, interactions and outcomes. In this way a theoretical framework of interrelated concepts developed. This showed possible relationships between pharmaceutical lobbying that represented the central phenomenon identified in answer to the questions: what was the central activity occurring here, what were the conditioning or influencing concepts, what were the observable outcomes and any intervening concepts and variables being represented by the other sub-categories identified (Strauss and Corbin, 1990). The selective coding stage focused on what emerged as the core category. The core category represented pharmaceutical lobbying, thus the main theme of the research. “A central category has analytical power. What gives it that power is its ability to pull the other categories together to form an explanatory whole” (Strauss and Corbin, 1998, p.146.).

3.7.4 Coding for process

“Processes are sequences of evolving action/interaction, changes in which they can be

traced to changes in structural conditions” (Strauss & Corbin, 1998, p.163). Coding for process was used specifically to analyse the process of lobbying as well as the sub-processes such as negotiation. For this purpose the researcher changed the analytical focus; instead of analyzing data for properties and dimensions the researcher was “purposely looking at action/interaction and noting movement and change as well as how it evolved (changes or remains the same) in response to changes in context or conditions” (Strauss & Corbin, 1998, p.167.). In the case of the research subject, pharmaceutical lobbying, the analysis of the process was essential for the building of substantive theory. The process of lobbying was broken down into sub processes for analysis:

Figure 1 *Time – Structural Conditions*



Arrow: evolving inter/action

Circles: Sub-processes

Overlaps in circles: intersection of conditions and consequences leading to change of variation in context and adjustments made in interaction to keep it flowing.

Adapted from Strauss & Corbin, 1998

The preliminary review, obtaining access, preparation and negotiation were sub-processes in the main pharmaceutical lobbying process. These sub-processes have been explained in the findings of this research. Process was always inextricably linked to structure which creates the context for action and interaction. Structure represented the context and conditions in which action/interaction took place. The structure in this

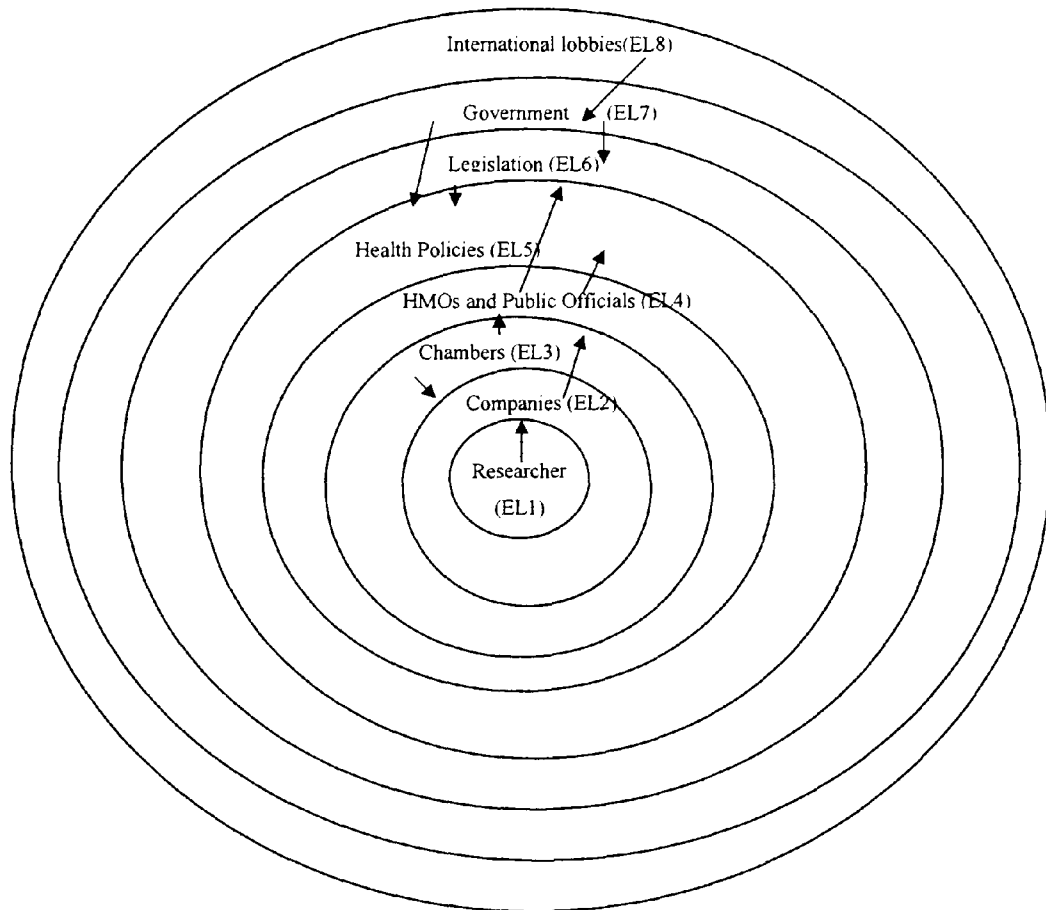
research was the pharmacopolitics arena in Argentina, which created the context for action and interaction between the pharmacopolitics managers and HMOs and public officials.

3.8 *The conditional matrix*

According to Strauss and Corbin (1998, p.181.) the “conditional/consequential matrix is an analytical device to stimulate an analysts’ thinking about the relationship between macro and micro conditions/consequences both to each other and to process”. The researcher could trace better the relationships of actions and interactions through the analysis of the full range of macro and micro conditions in which pharmaceutical lobbying was embedded. In the conditional matrix of this study the researcher was in the centre of the matrix; a fact that could pose subjectivity or bias in the analysis of the substantive theory. Reflexivity (Guba & Lincoln, 2001) was an important tool for the researcher in identifying the effect of self in the relationships of actions and interactions. The effect of self could affect what was researched and the substantive theory developed. Within the research project the researcher tried to maintain theoretical sensitivity and checked against the data gathered in the process of constant comparative analysis. In this way the researcher remained focused on the data and the development of the substantive theory of pharmaceutical lobbying rather than an analysis of himself or allowing the analysis to be derailed by preconceived ideas. The objective of the researcher was to be detached from his high degree of sensitivity to the topic and, through the iterative and constant comparison, focus on the data and the relationship of the different concepts, conditions, dimensions, properties, actions and interactions. Nevertheless, there is always a degree of subjectivity in the interpretation of the data, reflecting the “self” of the researcher.

In the case of this research, the conditional matrix considered the following elements:

First, the conditional matrix helped to direct the theoretical sampling and with the



design of the interview plan. Within the interviews it also helped to establish the relationships between the different elements present in pharmaceutical lobbying. It helped the researcher through the process of open coding and axial coding and to understand the relationship between conditions and consequences. Element one (EL1) was the researcher in his analysis of the whole process of lobbying. The companies (EL2) (structure) together with the chambers (EL3) (structure) carried out the lobbying process. Chambers (EL3) influenced companies (EL2) when they acted in a cooperative way. The other elements- HMO & public officials (EL4), health policies (EL5),

legislation (EL6), government (EL7) and international lobbies (EL8)- represented structural conditions that interacted in the process of lobbying. Regarding the paths of connectivity the arrows show a simplification of the different patterns of action/interaction over time. Companies (EL2) and chambers (EL3) influenced HMOs & public officials (EL4) with their lobbying to obtain favourable health policies. HMO and public officials (EL4) created the health policies. Public officials (EL4) also had a degree of influence on legislation enacted by the congress, as congress consulted the public officials on health issues. The government (EL7) implemented legislation affecting health policies. The government (EL7) also intervened in the creation of legislation presenting law projects to the congress. International lobbies (EL8) (e.g. PhRMA- the Pharmaceutical Manufactures Association USA) also pressured the government through the American Embassy to obtain favourable policies. The conditional matrix helped the researcher at the start of the research process by providing a framework that was possible to refer to. Through analysis the researcher was also able to see the links between the different elements of the research and established the relationships between concepts, sub-categories and the core category.

3.9 Theoretical Sampling

Unlike sampling done in quantitative investigations, theoretical sampling cannot be planned before embarking on grounded theory research. The aim of theoretical sampling in the research was to look for cases that would maximise opportunities for comparative analysis. In this research, the initial case was a pharmapolitics manager from a multinational company selected for his representativeness and experience in the area. The data analysis (open coding) pertaining to this case was taken as a basis. Additional cases were selected based on the possibilities of obtaining substantive information. The researcher used triangulation to support the findings and to gather new information

about the research subject. At all stages the researcher sought alternative explanations and tested for confirmation/rejection of the concepts developed by thorough analysis of the categories found in order to reduce the conceptual inadequacy of a theory (Strauss and Corbin, 1998). The researcher continued to sample until no new or relevant data appeared and thus achieved sub-categories and theoretical saturation. Not all sub-categories were equally relevant and so major sub-categories were saturated as completely as possible. The emergent theory was saturated, solid in the face of new data and rich in detail.

3.10 Substantive and Formal Theory: Identifying Issues

The aim of this research was first to generate substantive theory that emerged from the conceptual categories but that was grounded on the data. This substantive theory was developed for **pharmaceutical lobbying** that was the substantive area of inquiry (Glaser and Strauss, 1967). Throughout the research process the researcher adopted “the flexibility and freedom to explore a phenomenon in depth” (Strauss and Corbin, 1998, p.40.). Underpinning conceptual sub-categories to the core category (pharmaceutical lobbying) supported the emergence of a substantive theory. These emergent categories were the building blocks of substantive theory generation in the field of pharmaceutical lobbying. The researcher always had in mind the guidance of Glaser and Strauss (1967, p.237.) to evaluate the empirical grounding of grounded theory. This can be summarised as follows:

- (1) Fit - does the theory fit the substantive area in which it will be used?
- (2) Comprehension - will non-professionals concerned with the substantive area understand the theory?

(3) Ability to generalise - does the theory apply to a wide range of situations in the substantive area?

(4) Control - does the theory allow the user some control over the "Structure and process of daily situations as they change through time?"

To address those questions, the researcher compared the substantive theory with the formal theory using the formal theory as secondary data. This comparison showed the similarities of the substantive theory to the formal theory improving the construct definitions and therefore the validity of the findings. The researcher could also identify the conflicting issues establishing the domain to which the study's findings could be analytically generalised. This comparison enabled the researcher to abstract from the substantive theory and through a deductive and intellectual process, developed the conceptual findings of this research which are explained in the Conclusions chapter.

3.11 Conclusion

This chapter depicts the methodology used in this research, namely grounded theory. The researcher chose the Strauss & Corbin (1998) approach which permitted him to predetermine the general subject of enquiry before entering the research site so that the he could also opt for a structured set of analytical steps to be taken in coding and analysing phenomena. Nevertheless, some elements of Glaser's (1992) approach, such as theoretical sensitivity together with reflexivity, were used. The researcher decided to use grounded theory because he could commence from a specific 'grounded in reality' event, pharmaceutical lobbying, with the intent of understanding the nature and rationale of observed incidents. The conditional matrix showed the relationship between the macro and micro conditions in the research process facilitating the analysis. The coding and theoretical sampling were briefly commented. The researcher commented

the discussion between the substantive and formal theory aimed at developing the conceptual findings. In the next chapter, the data collection strategies, the data analysis process and the building of concepts, sub-categories and the core category are explained.

CHAPTER 4: DATA COLLECTION AND ANALYSIS

4.1 Introduction

In this chapter, the researcher described the context for the research which is the pharmacopolitics job in the multinational pharmaceutical industry in Argentina. He explained the data gathering strategies used (interviews, participant observation and archival data) and discussed researcher bias, reflexivity and ethical considerations. The interviews questions and the theoretical sampling were described. The researcher explained how the data were analysed and coded and how the sub-categories and the core category emerged.

4.2 Description of the research site and context for the research

When the researcher undertook this research the Argentine pharmaceutical market amounted to \$2.1 billion (IMS November 2005) and was the fourth largest market in Latin America. IMS, an international company that audits the sales of pharmaceutical companies as Nielsen does for consumer companies, estimates that there are more than 152 companies present in the Argentine market but there is a high concentration of sales within the top fifty companies. The research area is multinational pharmaceutical companies in Argentina and they account for a 46% of share of the prescription products market (the ethical market). There are 34 multinational pharmaceutical companies in Argentina. Eighteen of those had, within the last ten years, created the position of pharmacopolitics manager. They accounted for 34% of the ethical pharmaceutical market in Argentina (IMS November 05). Seven companies had a manager performing the job of pharmacopolitics on a part time basis. Nine companies did not have a pharmacopolitics manager.

The following graph shows the breakdown by company:

Table 7 *Pharmacopolitics breakdown by company*

| COMPANY | FULL TIME | PART-TIME | NONE |
|---------------|-----------|-----------|------|
| IVAX | X | | |
| PFIZER | X | | |
| SANOI AVENTIS | X | | |
| ROCHE | X | | |
| NOVARTIS | X | | |
| GSK | X | | |
| MSD | X | | |
| SCHERING ARG | | X | |
| BOEHRINGHER | X | | |
| BAYER | | X | |
| BMS | X | | |
| WYETH | | | X |
| ABBOTT | | | X |
| ALTANA | X | | |
| NOVO-NORDISK | | X | |
| ASTRA ZENECA | X | | |
| ALCON | X | | |
| JANSSEN | X | | |
| SANDOZ | | X | |
| SCHERINGPL | X | | |
| MERCK | | | X |
| VALEANT | | | X |
| ORGANON | | | X |
| ELILILLY | | X | |
| SERVIER | X | | |
| TRB | X | | |
| ALLERGAN | | | X |
| BAUSCH & LOMB | | | X |
| LUNDBECK | X | | |
| PIERRE FABRE | | X | |
| FERRING | | X | |
| MENARINI | X | | |
| GALDERMA | | | X |
| BAXTER | | | X |
| TOTAL | 18 | 7 | 9 |

These companies were affiliates to CAEMe, the multinational company's chamber. CAEMe was, according to Salisbury (1984), a corporation that carries out lobbying for all the multinational companies. The Chamber carried out the lobbying in a cooperative way and Chapter Five examines this process.

It is remarkable to note that, on analysing the profile of the pharmacopolitics managers from the 18 companies, there was a low turnover rate and that the managers have been in the same job for a long period of time; most of them since the creation of the position ten years ago. Building long-term relationships was a key issue for the success of lobbying and this is explained later in Chapter Five. Only Sanofi-Aventis had a pharmapolitics manager with less than three years in the position and the reason being that restructuring took place when the two companies merged. Another variable was that individuals appointed came from within the company.

The following breakdown shows the length of time the managers have held the job.

Table 8 Breakdown by time in the job

| COMPANY | TIME IN THE JOB | | |
|----------------|-----------------|---------|----------|
| | <3 YEARS | >3 & <6 | +6 YEARS |
| IVAX | | X | |
| PFIZER | | | X |
| SANOFI AVENTIS | X | | |
| ROCHE | | | X |
| NOVARTIS | | | X |
| GSK | | | X |
| MSD | | | X |
| BOEHRINGER | | | X |
| BMS | | | X |
| ALTANA | | | X |
| ASTRA ZENECA | | | X |
| ALCON | | X | |
| JANSSEN | | X | |
| SCHERINGPL | | X | |
| SERVIER | | | X |
| TRB | | X | |
| LUNDBECK | | X | |
| MENARINI | | | X |

American companies were the first to appoint pharmacopolitics managers and were more willing to do this because they had a similar position called *managed care*. The difference between the pharmapolitics manager in Argentina and the *managed care*

manager in the USA was that in the US a separate body undertook the lobbying of legislators through hiring professional lobbyists. Once large American companies started hiring pharmacopolitics managers there was a domino effect and European companies followed this trend.

4.3 Data Gathering Strategies

As noted in the previous chapter, there are three main categories of data in grounded theory research: field data (observational notes), interview data (notes, recordings, transcripts) and any existing literature that may be useful to the research. It should be remarked on that due to the characteristics of lobbying almost all communication was verbal and there were almost no written memos or mails between managers and/or officials. The only existing (or visible) outputs of the process were the favourable published legislation that arose as a result of said lobbying. Neri (2002), deputy of the Parliament and ex-Minister of Health, confirmed the issue in saying that the pharmaceutical industry had received no media attention or interest groups in their lobbying activities; the financial industry was for Neri (2002) at the top of the scale. The researcher studied the directory of all Non Governmental Organisations (NGOs) in Argentina and there was only one focused on governmental issues: Centro Integral de Políticas Públicas para la equidad y el Crecimiento. On its website, no mention was made of pharmaceutical lobbying in congress or in the Ministry of Health and its dependencies. Felicio (2002) said that the only time that the industry was in the media, attacking or being attacked, was because a pharmaceutical company had paid for the campaign. Tobar (2002) stated that pharmaceutical company lobbying was always concealed. Lobbying was only noticed by insiders or by word of mouth and the legislation issued was noticed only by the pharmacopolitics managers.

Notes and detailed tape recording transcripts were taken for the research. The researcher examined this data from a variety of perspectives in order to develop the most rigorous explanations of the phenomenon being studied. Interviews were the predominant source of data followed by participant observation. The overall consideration was the generation of primary data that captured the thoughts and explanations of the respondents. The researcher considered previous existing literature as secondary data and used this to confront the emergent theory with previous existing theory to improve internal and external validity.

The researcher obtained data through a combination of three independent methods:

- a) In depth interviews with pharmapolitics managers, marketing & sales managers, public and HMOs officials and external lobbyists.
- b) Participant observation of pharmapolitics manager's behaviour.
- c) Analysis of relevant documents.

These three data collection strategies have been described below.

4.3.1 Researcher bias

Grounded theory involved the subjective interpretation of interviewees' views and actions in order to generate theory. The researcher's interpretation relied on an experiential and values framework that defined the meaning assigned to the observations. This included the interpretation of any data whether observed, heard or read. To clarify, this related to interviews conducted, behaviours observed and documents read.

Reflexivity was the process of reflecting critically on the 'self' as a researcher (Guba &

Lincoln, 2001) within the research process. Because this thesis reflected the researcher's interpretation of complex interactions it was important to guard against the possible effects of his own subjectivity during the research process. Locke et al (1987) stressed the importance of the researcher being sensitive to his/her own biases, values, experiences and judgment. One way to deal with this bias is for researchers to elevate themselves to the centre stage through conscious recognition and explicit statement in their research reports (Guba and Lincoln, 1981). According to Bailey (1994) the identification and recording of researcher bias served two purposes. First, the explicit acknowledgment of bias ameliorated the potential effect of that bias. Second, recording biases in the research write-up made it easier for those evaluating the research to assess its objectivity.

The researcher had a deep interest in pharmaceutical lobbying and was working as a pharmapolitics manager for Alcon Laboratories in Buenos Aires and thus had a high degree of sensitivity to the research area. The researcher became aware of reflexivity (Guba & Lincoln, 2001), where the perspectives of the researcher could affect the research and the substantive theory being developed. Being the inquirer in all the cases, the researcher came to terms not only with those with whom he engaged in the interviews but with his own position in the research setting. Within the study the researcher tried to maintain theoretical sensitivity and checked out against the data gathered by the process of constant comparative analysis. In this way, the researcher remained focused on the data and the development of the substantive theory of pharmaceutical lobbying rather than an analysis of himself or allowing preconceived ideas to derail the analysis. The objective of the researcher was to be detached from his high degree of sensitivity to the topic and, through the iterative and constant comparison, focus on the data and the relationship between the different concepts,

conditions, dimensions, properties, actions and interactions. The main and most important issue was to diminish bias and for the researcher to remain aware of the effect of potential bias on the research process. The researcher tried to protect this work from any unwanted bias however, at the same time, recognising that subjectivity would always be present.

4.3.2 Ethical considerations

Within the terms of this research project ethical issues arose particularly in the conduct of field research. In relation to the university's policy on ethical issues the autonomy of individuals was respected through coding responses to provide anonymity and thus to protect them from harm. All participants received a code letter and the code letter was used in the transcriptions of all the interviews. The researcher kept the code key in a safe and the interview transcripts were stored in a computer room in a closed box without label. The researcher kept all notes taken in another closed box without label. The researcher wrote no e-mails concerning the transcripts of the interview tapes and all computer files were password protected. Confidentiality was granted and the researcher emphasised that no responses would be construed as representing either the particular respondent or their specific company. The idea was to eliminate respondents concerns about socially undesirable responses that might negatively reflect upon them or their companies.

All participants were thoroughly briefed on the nature and aims of the research project. The researcher gave a verbal and written description of the project (in Spanish) to the participants. The respondents also had a consent form and the right to withdraw at any moment. Consent was recorded in the written form signed by the participants and these were also kept in a closed box in the researcher's home.

The process for conducting field research was drawn up to ensure consistency across subjects and fair treatment. Attention was paid to ensure that the project was carried out with integrity, ensuring that the research methods proposed were followed in a way that was consistent with the methodology adopted, regardless of any pressure from subjects to take certain alternative stances. The researcher's employer was not used as a subject. Resources provided by the university were maximised, along with any data resources that were provided by the subjects in support of this research.

4.3.3 Interviews

The researcher chose semi-structured interviews as the main data gathering strategy because of the possibility of getting information without the constraints of a questionnaire. In an interview the researcher was able to follow up the ideas, probe responses and investigate motives (apparent or hidden). The researcher was also able to introduce additional questions during the interview so that each idea was dealt with extensively and new ideas could also emerge.

The researcher, through his role as a pharmapolitics manager, was granted easy access to other managers as well as public and HMOs officials. Most interviews took place in offices of the respondents but in neutral locations (hotel lobbies) in two cases. The respondents received no fees for the interviews. Issues regarding current work were discussed at the beginning of the meeting so that the second part of the interview was devoted only to the research project. The researcher recorded the interviews after receiving the written consent of the respondents. Planning the interviews was time consuming as agendas were full and it took longer than expected for the interviews to take place.

The interview process was divided into two stages as the following table shows:

| Type of interviews | Date | Number of interviewees | Objective | Method |
|---------------------------|--------------------------|------------------------|-----------------|----------------------------|
| Pilot interviews stage | June 2002 | 6 | Research design | Semi-structured interviews |
| Research interviews stage | May 2005 to January 2006 | 22 | Research data | Semi-structured interviews |

Six pilot interviews took place in June 2002 with two top officials at the Ministry of Health (Dr. Federico Tobar and Dr. Nestor Vazquez), one Deputy of Congress and ex-Minister of Health (Dr. Aldo Neri), one advisor to a deputy of Congress (Mr. Carlos Vasallo), the President of the Multinationals Chamber (Mr. Nestor Felicio) and the external affairs manager of the Multinationals Chamber (Dr. Victor Quiñones). The interviews were semi-structured with a list of topics to be developed as the interview progressed. These interviews were useful in the design of the research proposal and defined the context in which pharmaceutical lobbying was taking place. These six interviews were the basis of the development of the research design.

The research interviews took place between May 2005 and January 2006. Data gathering and analysis was performed concomitantly with the process of interviewing. The researcher developed a fixed set of questions for the semi-structured interviews. Preliminary sub-categories were built in the first three interviews and the later

interviews focused on the discovery of additional data which could create new sub-categories or saturate the existing ones. Saturation of theory with the interviews of pharmacopolitics managers came after the sixth interview. The two additional interviews realised no additional information.

Triangulation with public and HMO officials was important as it gave additional depth to the theory and reinforced the concepts related to how pharmacopolitics managers performed their duties. The researcher decided to incorporate health care lobbyists that occasionally worked for the pharmaceutical industry as additional respondents. These additional respondents worked for distributors, wholesalers, chambers and other performers in the pharmaceutical industry. These interviewees were not in the original planning of the research but they proved to be extremely valuable to describe, from the perspective of outsiders, the lobbying performed by pharmacopolitics managers and the pharmaceutical industry. The information gathered from these people was also extremely useful in consolidating the emergent theory with another perspective. Lobbyists from the chamber, distributors and free-lancers enriched the research with new information that contributed to the saturation of the already found sub-categories and provided new concepts, sub-concepts, properties and dimensions. The following table shows the breakdown, by type, of interviewee in the second stage of the interview process:

Table 9 *Breakdown by type of interviewee*

| Type of interviewee | Number of Participants |
|----------------------------|-------------------------------|
| Pharmapolitics managers | 8 |
| Sales/marketing directors | 3 |
| HMO officials | 3 |

| | |
|--------------------------|---|
| Public officials | 4 |
| Other industry lobbyists | 4 |

The researcher interviewed all informants once and the first three respondents two times. The second interviews with pharmacopolitics managers enabled the verification, clarification and elaboration of information obtained during the first interview as well as the crosschecking of information acquired from other industry lobbyists. It also helped to resolve factual inconsistencies. Interviewing ceased when saturation of the major theoretical sub-categories had occurred.

The researcher contacted all interviewees personally, explained the research to them and invited them to participate. Respondents were advised that participation in the study was voluntary and that they could withdraw from the study at any time. In addition, the researcher explained that the report would maintain their anonymity and that no means of identification would be retained in the transcripts of the interviews. All of the people approached agreed to take part on this basis and all freely gave their permission for the interview to be recorded. The researcher gave the interviewees a consent form with the withdrawal clause. Interviews ranged from 30 minutes to a maximum of one hour. The interviewees were all very open, spoke freely and provided deep rich data. Nevertheless, in almost all interviews the researcher perceived a guarded reticence on the issue of contribution payments. All respondents explained the issue itself but the language used avoided the issue: that a corrupt act was taking place or that any inference of a bribe was occurring.

The researcher used theoretical sampling to look for cases that maximised opportunities for comparative analysis. The aim of the research was not reliability but the validity of

the findings. No pilot sample was performed in this stage of the research as the total population of pharmacopolitics managers was very small and highly specific so the researcher could not afford to use up any part of the sample.

The interviewees were also chosen because of their representativeness and by their expertise in the job. All respondents had been more than 5 years in the job.

Table 10 Breakdown by years of experience

| Years of experience | Pharmacopolitics Managers | Other interviewees |
|----------------------------|----------------------------------|---------------------------|
| 0-5 | 0 | 0 |
| 5-10 | 8 | 4 |
| 10+ | 0 | 10 |

The educational qualifications of the pharmacopolitics managers were not an issue at the time of their appointment as they had been recruited from sales forces as experienced and trusted people. On the contrary, the other respondents had higher academic experiences that enabled them to go further in the ranks due to their technical qualifications.

Table 11 Breakdown by Academic Qualification

| Academic qualification | Pharmacopolitics Manager | Other informants |
|-------------------------------|---------------------------------|-------------------------|
| Doctoral Degree | 0 | 2 |
| Masters Degree | 0 | 3 |
| University Degree | 4 | 8 |

| | | |
|------------------|---|---|
| Secondary Degree | 4 | 1 |
|------------------|---|---|

Interviewing ceased when saturation of the major theoretical sub-categories had occurred.

4.3.3:1 The Interview Questions

“Grounded Theory entails two basic analytical procedures. Firstly, one continually makes comparisons and secondly one asks questions” (Howell, 2000, p.129). The research questions for this research were:

- a) Why do multinational pharmaceutical companies in Argentina lobby officials?
- b) How do multinational pharmaceutical companies carry out lobbying activities?

Additional basic questions such as “what” and “who” arose from the process of the development of the research but these were not issues *a priori*. The question “why” reflected the incentives of pharmaceutical companies to influence legislation. The question “how” reflected how the process was undertaken: whether it was alone or in a cooperative way, or through contribution payments or the transmission of information. These research questions were the basis, together with the previous existing literature, for the creation of a fixed set of questions for the interviews. The researcher modified the approach to these questions to adapt to the different perspectives, whether the interviewee was a pharmapolitics manager or 'other'. The questions helped to ensure same information was in all the interviews and facilitated the process of coding and building the categories. The questions were open and aimed at enhancing the richness of the data; they also permitted the researcher to probe in depth each of the responses. The interviews generated the most important data for this research. The questions were as

follows:

Figure 2 *Fixed Set of questions*

- a) *Who are the officials that pharmaceutical companies choose as targets for lobbying?*
- b) *What do you think are the key motivations for pharmaceutical companies to lobby public and HMO officials?*
- c) *What are the objectives that you seek when you lobby officials?*
- d) *Who are the participants in the process of pharmaceutical lobbying?*
- e) *What do you think are the key issues for success when you engage in lobbying?*
- f) *How would you describe the process of pharmaceutical lobbying?*
- g) *Which strategy do you follow if you want to influence an official?*
- h) *How much relevance do you give to scientific information in the process of lobbying?*
- i) *Are there other non-scientific instruments that you use to achieve your objective?*
- j) *When a lobbying process is not successful, what do you do next?*
- k) *Is pharmaceutical lobbying carried out alone or in a cooperative way?*
- l) *Do you think that it is possible to free-ride?*

Questions a), d), e), f), g), h), i), j), k) and l) are aimed to answer the research question: How do multinational pharmaceutical companies carry out lobbying activities? Questions b) and c) look to answer the research question: Why do multinational pharmaceutical companies carry out lobbying activities? Formal lobbying theory was used initially to help formulate the fixed set of questions and the relationship of the interview questions to the formal theory is the following:

Question a) *Who are the officials that pharmaceutical companies choose as targets for lobbying?* was not included by the researcher in the first three interviews. After the open coding of these interviews, the researcher realised that there was one element present in the interviews and missing in the questions. The researcher on reflection realised that the question “Who is the target for pharmaceutical lobbying?” was missing. The micro-theory of lobbying corroborated this issue pointing out that members of congress and the HMOs officials were the target for lobbying in the USA (Public Citizen Congress Watch (2002, 2004), Dranove (2003), Studin (2002)). The question was aimed at developing theory about which officials are the target of lobbying in Argentina.

The questions b) *What do you think are the key motivations for pharmaceutical companies to lobby public and HMO officials?* and c) *What are the objectives that you seek when you lobby officials?* followed the macro, meso and micro-theory of lobbying in which interest groups or lobbying actors have a motivation to influence the officials (Olson (1965), Moe (1980), Salisbury (1984), Howell (2004), Kirchner (1980), Woll (2006), Grossman & Helpman (1994, 1995), Maggie and Rodriguez Clare (2000), Potters and van Winden (1992), Ainsworth (1993), Austen-Smith and Wright (1992), Lohmann (1993, 1995), Lagerlof (1997), Bennedsen and Feldmann (2001), Public Citizen, (2002, 2004), Studin (2002), Dranove (2003), Glabman (2004)). The micro-theory described specific reasons as a protection against competition, preservation of the freedom of prices, tax breaks and the introduction of products in formularies (Public Citizen, (2002, 2004), Studin (2002), Dranove (2003), Glabman (2004)). The two questions aimed to identify the motivations of the pharmaceutical industry.

The question d) *Who are the participants in the process of pharmaceutical lobbying?* was based on the macro-theory of lobbying in which Woll (2006) identified that lobbying is carried out by interest groups and other actors. The question tried to identify the lobbying actors; either interests groups or companies in the process of

pharmaceutical lobbying.

The question e) *What do you think are the key issues for success when you engage in lobbying?* was based on the micro-theory of lobbying, in which the pharmaceutical industry in the USA had different elements to achieve success such as information, the lobby of the American Chamber, PACs, external lobbyists, the use of managed care account managers and rebates to HMOs (Public Citizen (2002, 2004), Studin (2002), Glabman (2004), Pilnick, Dingwall & Starkey (2001)). The question was aimed at identifying the key issues for success in Argentina.

Questions f) *How would you describe the process of pharmaceutical lobbying?* and g) *Which strategy do you follow if you want to influence an official?* were based on the meso-theory of lobbying that explains how lobbying is carried out and aimed at discovering how this lobbying process is in Argentina (Grossman & Helpman (1994, 1995), Maggie and Rodriguez Clare (2000), Potters and van Winden (1992), Ainsworth (1993), Austen-Smith and Wright (1992), Lohmann (1993, 1995), Lagerlof (1997), Bennedsen and Feldmann (2001)). The two questions aimed at a spontaneous description by the interviewee about whether he/she uses transmission of information or contribution payments as a lobbying instrument.

Question h) *How much relevance do you give to scientific information in the process of lobbying?* was based on the meso-theory of lobbying and the transmission of information (Potters and van Winden (1992), Ainsworth (1993), Austen-Smith and Wright (1992), Lohmann (1993, 1995), Lagerlof (1997), Bennedsen and Feldmann (2001)). The researcher intended to establish the importance in the lobbying process given to the transmission of information.

Question i) *Are there other non-scientific instruments that you use to achieve your objective?* was an implicit way of asking about the issue of contribution payments as it was one of the two channels of influence described in the meso-theory of lobbying

(Grossman & Helpman (1994, 1995), Maggie and Rodriguez Clare (2000)). The aim of this question was to explore the use of contribution payments in pharmaceutical lobbying.

Question j) *When a lobbying process is not successful, what do you do next?* was based on the meso-theory of lobbying in which the lobbyists had to carry out counteractive lobbying when the decision of the official was not favourable to their interests (Aidt, (1997) Austen-Smith and Wright (1992)). The question was designed to discover which strategy was taken when there was initially no success.

Question k) *Is pharmaceutical lobbying carried out alone or in a cooperative way?* was based on the meso-theory of lobbying in the building of coalitions to lobby (Rama and Tabellini (1998), Howell (2004), Aidt (1997), Graziano (2001), Hula (1999), Hojnacki (1997), Almeida (2005)). The researcher aimed at identifying when coalitions were used.

Question l) *Do you think that it is possible to free-ride?* was based on the Olson (1965) theory of free-ride in interest groups. The objective of this question was to find out whether it was possible to free-ride on the lobbying of other interest groups or lobbying actors.

4.3.4 Participant Observation

Participant observation was used as a significant additional means of data collection in the study. The researcher as a pharmapolitics manager interacted with most of the respondents on a regular basis through meetings in the Chamber of Multinational Pharmaceutical Companies or other meetings with topics related to pharmacopolitics. The researcher could also see the interaction of the managers with public officials and HMO officials and the way lobbying was performed in numerous cases. The researcher

also saw how in a cooperative way lobbying was exerted by the Chamber or by groups of companies in order to achieve a certain objective favourable for the industry or for a group of companies. The researcher kept a diary and made field notes about relevant situations in which he was involved.

As Spradley (1980) noted, the participant observer's objective in entering as a researcher-participant in a social situation was essentially to engage in activities that were appropriate to the situation and, from this vantage point, to observe and interpret the activities, people, and physical aspects of the situation. The researcher decided to undertake the study during his current job at Alcon and was thus in an ideal position to collect data as a legitimate observer who was immersed in the culture of the system. Saville-Troike (1982) suggested that one of the advantages of studying one's own culture from the inside, so to speak, in an effort to make explicit what has not been stated and perhaps unconscious systems of understanding, was the researcher's ability to use himself as a direct source of information and interpretation. To use this method effectively the researcher was aware of the context, institutions and values that guide cultural behaviour in the community that was being studied. The researcher also had to be also aware of his 'self' in the research process, to try to diminish subjectivity in the interpretation of the findings. Reflexivity was always taken into account by the researcher and through focus on the data and the iterative comparison process, the researcher tried to minimise subjectivity but at the same time, he recognised that subjectivity would always be present.

In the present study, the researcher was clearly accepted as a member of the establishment and as a genuine participant in the process of pharmaceutical lobbying. The researcher also believed that the fact of being a participant facilitated the gathering of the data as respondents did not appear to be constrained in their reactions or

behaviour towards the researcher. The field notes that were described earlier played a vital role in the interpretation of the process as the research progressed.

4.3.5 *Analysis of relevant documents*

As mentioned before, almost all communication in pharmaceutical lobbying was verbal and there were almost no written memos or mails between managers and/or officials. Neither interest groups nor the media have dedicated their attention to pharmaceutical lobbying. The only existing (or visible) outputs of the process of lobbying were the favourable published legislation clauses that arose through the process of lobbying. This legislation was public and was published in the Boletín Oficial, a government publication where all laws, decrees and edicts must be published to be implemented. Respondent K (EX) stated that the most relevant issues in the last years have been modifications to the National Formulary prompted by multinational companies. This formulary was very restrictive and the lobbying of certain multinationals caused some drugs to be introduced. Another issue was the modifications introduced to the Reference Prices decree and to the Generics Law (Respondent B, PH) but this time the lobby was done by the whole industry (national and multinational). These modifications improved the competitive situation of established companies towards new generic companies. This additional information from the output of the lobby was cross-checked with the information provided by the respondents so that information could be validated and grounded in the data.

4.4 *Data Analysis*

This part focuses on how the data was analysed and how the grounded theory methodology was used to build a substantive theory. The emergent theory has been

presented in chapter five.

When the research was first planned it was thought that there would be two areas of analysis:

1. pharmaceutical lobbying of the HMOs
2. pharmaceutical lobbying of public officials

There were two targets initially because there seemed to be differences in the way pharmacopolitics managers approached public and HMO officials. The data, after analysis and coding of the interviews and going through the inductive process of grounded theory, showed no great difference between the approaches of the pharmacopolitics managers towards either group of officials. Therefore both groups were treated as the sample and were integrated in one group referred to as “officials”.

4.4.1 Initial Analysis

The first case chosen was interviewed in May 2005 following theoretical sampling. The interviewee was a pharmapolitics manager of a medium size company who had previously worked for a large company and was chosen because of his apparent expertise and understanding of the lobbying process. The researcher used the fixed set of questions for the interview. The interview was semi-structured and provided rich data for the analysis and coding. The interview was transcribed and analysed word-by-word, line-by-line and phrase-by-phrase. Not only did the researcher look for literal meaning but also for the hidden meanings and sub-texts that the interviewee expressed. Much interpretative work was undertaken to elucidate the meaning of certain phrases. The fact that the researcher was a pharmacopolitics manager certainly helped in this process. The researcher's familiarity with the research subject also enhanced the theoretical

sensitivity and he carried out the open coding process giving labels to activities, contexts, functions, relationships, influences and outcomes. Those labels were integrated into conceptual codes to each incident highlighted within the data. The richness of the interview permitted the identification of an important quantity of concepts, properties, phenomenon, dimensions and intervening conditions. The constant interaction with the data and listening to what the data implied enabled a refinement of the initial concepts and properties.

The second and third interviews took place in July 2005 and transcribing and open coding of these interviews took place immediately afterwards. The responses were analysed meticulously and compared them constantly with the first in order to validate the concepts, sub-concepts and properties. The interviews confirmed concepts already found or add new concepts that arose from the data. Some concepts grew in relevance compared to the first interview and others lost significance.

The researcher reviewed the first interview again and realised that similar incidents and phenomena were present in different concepts and sub-concepts so that he assimilated them into broader concepts. The researcher reviewed the interviews looking for context, conditions, interactions and consequences to be able to identify the structure where the research was taking place. The researcher then began with the process of axial coding identifying relationships between concepts, sub-concepts and properties for the purpose of developing categories. Sub-categories emerged as aggregates of the most closely interrelated elements. As the researcher finished this stage of open-coding and axial coding it was possible to identify 10 sub-categories, 28 concepts and 30 sub-concepts,

all based in the data (Appendix 2)¹. The following chart shows the complete list of initial sub-categories:

| |
|-----------------------------------|
| Health Care Structure |
| Market |
| Competence |
| Product Value |
| Interests Representation |
| National Policy |
| Demand |
| Interest Groups |
| Negotiation |
| International/ National Pressures |

These 10 sub-categories were so strongly supported over the duration of the research that they were found as sub-categories in their own right, or properties of other sub-categories at the conclusion of the research.

Three additional pharmacopolitics managers were interviewed during August 2005. The researcher carried out the open coding process looking for new concepts, properties or dimensions. The researcher noticed that no additional information arose from the open

¹ The labels included in the Appendix show only a selection of those identified in the process of open coding.

coding process so that the researcher was not satisfied with the outcome. The results of the interviews, although rich in information, did not consider certain aspects that the researcher, as an observer, was able to identify. It seemed to the researcher that the pharmacopolitics managers did not consider the whole process and they were only considering the issues from a point of view that was based solely on their daily work. At this stage, the possibility of building new theory from the data seemed limited. Elements such as free-riding or cooperative lobbying were missing. The researcher decided to interview two additional pharmacopolitics managers in September 2005 however the results were not overly different to the previous interviews.

To deal with this problem the researcher changed tactics and decided not to continue with interviews before analysing two interviews carried out in July 2005; of a public official and an HMO official. The researcher reviewed the transcripts and carried out the open coding process and concluded that the information only validated the concepts already found.

At this stage, the researcher decided to follow a piece of advice given to him by his supervisor in April 2005: "If you have access to the people, just interview everyone who is related to the subject, do the transcription and coding and hopefully you will discover substantive theory".

The researcher decided to interview not only officials as planned in the research design but other participants in pharmaceutical lobbying. Interviews were carried out between October 2005 and December 2005. Officials were interviewed first because they were active participants in the pharmaceutical lobbying process. The relationship with pharmacopolitics managers and pharmaceutical companies was regularly discussed and some of them talked about the economic restraints of the HMOs or the government,

emphasising the role of industry as a third payer through rebates. The researcher noticed a negative attitude towards the contributions of the industry aimed at alleviating the financial restraints of the HMOs; the general feeling was that the pharmaceutical industry was a necessary evil. The interviews were open coded and transcribed and they helped to consolidate the concepts already found.

Officials support the validity of the already existing concepts but important elements were missing. The researcher then decided to interview lobbyists not from the pharmaceutical companies but from companies related to them. Two were health care free-lance lobbyists who sometimes worked for the pharmaceutical industry; one was the general manager of a distribution company and the other a general manager of the multinational companies' chamber. These four people were external to the pharmacopolitics inner ring but acted as pharmaceutical industry lobbyists on certain occasions. Through the interviews the researcher was able to explore aspects that were absent in the other interviews. These interviewees were not participants of the lobbying process but outsider observers. This distance and lack of involvement in the pharmapolitics manager-official lobbying process gave them a wider perspective of "what was really happening" (Glaser, 1978, p.57). They provided a great deal of information which helped both to validate the existing concepts, sub-concepts and properties and provide new data for the open coding process. The researcher carried out the open coding of the external lobbyists interviews labelling concepts, sub-concepts, dimensions and properties. The researcher regrouped the data and began the process of axial coding again; at first he looked for the saturation of the existing sub-categories analysing the concepts, properties and dimensions. Secondly, he identified relationship between the new concepts, sub-concepts and properties developing new sub-categories and concepts. The researcher had, at this stage, 15 sub-categories 43 concepts and 44

sub-concepts (Appendix 2)². The sub-categories were the following:

Figure 3 *Second set of sub- categories*

| |
|---|
| Health Care System |
| Hierarchical Structure of Decision-making |
| Market |
| Objectives |
| Product Value |
| Strategy |
| Building relationships |
| Interest Agreement |
| National Policy |
| Needs of Officials |
| Interest Groups |
| Negotiation |
| Contribution and communication |
| International/ National Pressures |
| Cooperative lobbying |

Following the research design, sales directors of companies with no pharmacopolitics managers were also interviewed. The researcher decided to leave them for last, as the

² The labels included in the Appendix show only a selection of those identified in the process of open

aim of interviewing them was to assess the free-rider effect. During December 2005 the researcher interviewed two sales directors and one marketing director from companies without pharmacopolitics managers to evaluate their perceptions about pharmacopolitics. All of them recognised that it was an important issue in the Argentine pharmaceutical market. Two respondents told the researcher that they relied on the Chamber for lobbying with the HMOs. The other one was evaluating the possibility of introducing the position in his company for the next year. Asked about free-riding, the researcher was told that they did not see it as a possibility as anyone free-riding is punished because of their attitude. The researcher coded these interviews and they provided some data for the saturation of the free-riding concept which was previously identified. No additional concepts arose from these interviews. The researcher dealt with this in detail in the substantive theory chapter.

4.4.2 Re-categorising the data

After having finished the planned interviews, the researcher decided to interview the first three pharmacopolitics managers again with these new elements provided by external lobbyists. The interviews were aimed at assessing the perspectives outlined by the external lobbyists. That was done in January 2006. The researcher carried out the open coding of the interviews and he considered that the data gathering process was finished as the sub-categories were saturated.

At this stage, the researcher went back to the data and started to re-categorise labels and refined the sub-categories and concepts. As mentioned previously, the researcher had, at this stage, 15 sub-categories, 43 concepts and 44 sub-concepts. The researcher was

aware that for the selective coding, it was essential to refine the sub-categories and concepts. The researcher knew that with the information he had the main issue was to refine the sub-categories so that it would be possible to proceed to the selective coding stage. The researcher came back to the sub-categories and began again with the process of axial coding looking at the concepts, properties, dimensions and relationships between the sub-categories in order to refine further these categories. After this process seven sub-categories emerged which were rich in detail and supported by the data. The following chart depicts the integration of the categories.

Table 12 *Integration of the categories*

| <u>New Sub-Categories</u> | <u>Original Sub- Categories</u> |
|---------------------------|---|
| Target for lobbying | Hierarchical Structure of Decision-making |
| Motivations | Objectives |
| Participants | Health Care System Interest groups |
| Product value | Product value |
| Building trust | Building relationships |

| <u>New Sub-Categories</u> | <u>Original Sub- Categories</u> |
|---------------------------|--|
| Strategy | Strategy Contribution and Communication Needs of Officials Market Negotiation Interest Agreement National Policy International/National pressures |
| Cooperative lobbying | Cooperative lobbying |

The linking together of these sub-categories now emerged as the main objective. The researcher began with the selective coding as Strauss and Corbin (1990, p.15.) stated “Selective coding is the process by which all categories are unified around a core category”. Selective coding required the selection of the seven sub-categories that emerged from the axial coding process. All other sub-categories or concepts were related in some way to these categories, either directly or indirectly. In this way a theoretical framework of interrelated concepts developed showing relationships between the concepts and the sub-categories. These concepts were identified in answer to the questions of ‘what was the central activity occurring here, what were the conditioning or influencing concepts, what were the observable outcomes and were any intervening concepts and variables being represented. The selective coding stage focused in defining the core category. The seven categories (target for lobbying, motivations, participants, product, building trust, strategy and cooperative lobbying) derived from the core category, which in this research was *pharmaceutical lobbying*. This core category

integrated the seven sub-categories and it represented the main theme of the research. Pharmaceutical lobbying as a category has analytical power. It has the power to pull the other sub-categories together to form an explanatory whole. The seven sub-categories interacted and thus created the core category of pharmaceutical lobbying. Selective coding integrated the research; it put the story straight, provided analysis, identified the core category and illustrated how major categories were related.

4.5 Conclusion

This chapter described the research site and the context so that the reader can understand the context in which the research was carried out; the focus was the people who held the job of pharmacopolitics in the multinational pharmaceutical companies in Argentina. It depicts the data gathering strategies used: interviews, participant observation and relevant documents. Interviews were the main source of information for this research. The interviewees' practical knowledge was analysed and the theoretical frameworks constructed looking for saturation across cases. Six pilot interviews and twenty five in-depth semi-structured interviews were carried out. These interviews provided the basis for the data analysis and coding. Participant observation brought additional data for the validation of the data. Relevant documents were scarce and the only documents found were the legislation that arose from the lobbying process.

The data analysis process was also described in the analysis of the data and the consequent building of concepts, dimensions and sub-categories. Theoretical sampling looked for the richness of the data. Interviews were transcribed and analysed. Open coding was implemented to find concepts, properties and dimensions. The researcher followed the steps of Strauss and Corbin (1998) but realised that the process was not linear at all and had to emulate Donald Schön (1991) in the "Reflective Practitioner"

when he changed a student's prototype of a building in order to adapt it to a slope. The researcher also decided to introduce changes to the research design as he realised that important information was missing. The analysis of the open coding stage indicated to the researcher that it was necessary to broaden the scope of interviewees by introducing external lobbyists. This additional data proved to be very important in the formulation of the sub-categories and the saturation of them. Axial coding was used to integrate the concepts, properties and dimensions in the sub-categories. This was an iterative process of refining the categories until in the end seven were found: target for lobbying, motivations, participants, product, building trust, strategy and cooperative lobbying. The researcher then went through the process of selective coding aimed at finding the core categories. The researcher found only one core category that relates to all of the others together and that is *pharmaceutical lobbying*. On the next chapter, the researcher describes how the substantive theory was developed.

CHAPTER 5: *DEVELOPING SUBSTANTIVE THEORY*

5.1 *Introduction*

Goulding (2002) stated that there was no strict formula for the presentation of grounded theory. On the other hand Glaser and Strauss (1967, p.31) provide two ways to present grounded theory results: “Grounded theory can be presented either as a well-codified set of propositions or in a running theoretical discussion using conceptual categories and their properties”.

The researcher presented the findings using a running theoretical discussion to develop the sub-categories, concepts and properties. The researcher outlined a substantive theory in such a way that it demonstrated how concepts emerged and developed from the data, how the researcher moved from the descriptive through the inductive-deductive process of abstraction and how the core category was generated. This chapter describes in detail the process that led to the development of substantive theory and provides corresponding quotations that give additional weight to the conceptual theory to make it clear that emergent theory is grounded in the data.

This research was an attempt to describe why and how multinational companies in Argentina carry out pharmaceutical lobbying. The research has gone some way towards bridging the gap between theory and practice.

5.2 *Interview questions and interviewee time table*

“Grounded Theory entails two basic analytical procedures. Firstly one continually makes comparisons and secondly one asks questions” (Howell, 2000, p.129). The interview process provided the main source of data for this research. The research

questions, the pilot interviews and formal theory were the basis for the fixed questions. These questions were adapted in relation to the respondents' profiles and some questions changed if the respondent was an official or a sales or marketing director. As mentioned previously the autonomy of interviewees was respected through coding responses to provide anonymity and thus to protect them from harm. This coding might be confusing when reading the quotes of respondents. The following table presents the interviewee coding and the interview timetable to facilitate the reader the identification of the respondents. For quoting, the researcher has adopted the following abbreviations: Pharmacopolitics Manager (PH), External lobbyist (EX), HMO Official (HO), Public Official (PU) and Sales Director or Marketing Director (SD)

Table 13 *Interview timetable and coding*

| INTERVIEWEE | PROFILE | DATE OF THE INTERVIEW |
|-------------|--------------------|--------------------------|
| A | PHARMACOPOLITICS | May 2005 / January 2006 |
| B | PHARMACOPOLITICS | July 2005 / January 2006 |
| C | PHARMACOPOLITICS | July 2005 / January 2006 |
| D | PHARMACOPOLITICS | August 2005 |
| E | PHARMACOPOLITICS | August 2005 |
| F | PHARMACOPOLITICS | August 2005 |
| G | PHARMACOPOLITICS | September 2005 |
| H | PHARMACOPOLITICS | September 2005 |
| I | EXTERNAL LOBBYIST | November 2005 |
| J | EXTERNAL LOBBYIST | November 2005 |
| K | EXTERNAL LOBBYIST | December 2005 |
| L | EXTERNAL LOBBYIST | December 2005 |
| M | HMO OFFICIAL | July 2005 |
| N | HMO OFFICIAL | September 2005 |
| O | HMO OFFICIAL | October 2005 |
| P | PUBLIC OFFICIAL | July 2005 |
| Q | PUBLIC OFFICIAL | October 2005 |
| R | PUBLIC OFFICIAL | October 2005 |
| S | SALES DIRECTOR | December 2005 |
| T | SALES DIRECTOR | December 2005 |
| U | PUBLIC OFFICIAL | November 2005 |
| V | MARKETING DIRECTOR | December 2005 |

The profile shows the characteristics of the respondent, whether he/she was a pharmacopolitics manager, an official, an external lobbyist or a Sales/Marketing Director. The questions helped to provide the same information in all the interviews and

facilitated the process of coding and building the categories. The questions were open, aimed at enhancing the richness of the data and the questions permitted the researcher to probe further the responses. The semi-structured interview questions were:

- 1. Who are the officials that pharmaceutical companies choose as targets for lobbying?*
- 2. What do you think are the key motivations for pharmaceutical companies to lobby Public and HMO officials?*
- 3. What are the objectives that you seek when you lobby officials?*
- 4. Who are the participants in the process of pharmaceutical lobbying?*
- 5. What do you think are the key issues for success when you engage in lobbying?*
- 6. How would you describe the process of pharmaceutical lobbying?*
- 7. Which strategy do you follow if you want to influence an official?*
- 8. How much relevance do you give to scientific information in the process of lobbying?*
- 9. Are there other non-scientific instruments that you use to achieve your objective?*
- 10. When a lobbying process is not successful, what do you do next?*
- 11. Is pharmaceutical lobbying carried out alone or in a cooperative way?*
- 12. Do you think that it is possible to free-ride?*

Questions 2 y 3 although similar are different in the context of the language, Spanish, in which they were formulated. Motivations, in Spanish, referred to the reasons why pharmaceutical companies carried out lobbying to officials. Objectives described the specific goals to be achieved through lobbying e.g. the introduction of a certain product in a formulary. The researcher used both questions to collect the information from two

different perspectives: the strategic one (motivations) and the tactical (objectives). In question 8, scientific information referred to the information about a product or technology given to the official aimed at influencing a policy decision. Cooperative lobbying in question 11, focused on the lobbying carried out in a coalition, either the chamber or a group of companies. Free-ride in question 12, referred to those companies that attempted to benefit from the cooperative lobbying without contributing with the costs of this lobbying.

5.3 *The interview results*

The researcher asked the same questions in the same order to all interviewees in order to facilitate the process of the open coding of the data. The questions in the interviews permitted the collection of sufficient data to build the substantive theory and the interviews allowed the construction of sub-categories around the core category of *pharmaceutical lobbying*. The twelve questions permitted the building of seven sub-categories.

*Question one (Sub-Category = **Target for lobbying**)*

*Who are the officials that pharmaceutical companies choose as **targets for lobbying**?*

At the beginning of the research, there were only eleven questions. At that stage, the researcher began the interviews with question number two which was about the motivations of pharmacopolitics managers in lobbying officials. After the coding of the initial three interviews the researcher decided that there was an additional element to take into account. In the first three interviews the respondents mentioned that it was important to lobby officials and not physicians. The researcher, on reflection, decided that the question: “Who is the **target** for pharmaceutical lobbying?” was missing. The researcher included this question in the next interviews and it became clear that the

target for lobbying was the officials. None of the respondents considered physicians as decision referents in the lobbying process. Not even opinion leaders³ were essential in the introduction of **products** in the formularies. In the cases where physicians were acting as officials then the pharmaceutical companies regarded them as exactly this and took no notice of their profession in the lobbying process.

“...these new pharmapolitics managers are not related to the old managers or sales managers, whose task was to convince the physicians about the therapeutic qualities of a **product** or to train and motivate the sales representatives to achieve this objective. Today, this manager is a highly skilled negotiator who has to deal with the official of the HMO who is another negotiator with opposed interests to that of the pharmaceutical company” (Interviewee J, EX).

One respondent mentioned opinion leaders as important but only in the context of companies that did not lobby the officials.

“...there are a few pharmaceutical companies that do not lobby and they have a niche **product**; this **product** is not incorporated in the formularies and not even in the PMO (national formulary). These companies work with opinion leaders as the pathologies are very specific. These pathologies are treated by, let us say, 500 to 1000 physicians in the whole country. These companies work with the medical associations focusing their promotions on the physician” (Interviewee A, PH).

³Opinion leaders, or "thought leaders", are respected individuals, such as prominent medical school faculty, who influence physicians through their professional status. Pharmaceutical companies generally engage key opinion leaders early in the drug development process to provide advocacy and key marketing feedback.

Consequently, officials were the lobbying **target** of the pharmaceutical companies. Even then the researcher realised that there was, in all the pharmacopolitics manager interviews, always a comparison between the relationship between pharmaceutical company-physicians and pharmaceutical company-officials. On analysing these comments, the concept of the transfer of decision power from the physician to the official began to gain relevance. The researcher returned to the data and explored the concept until he reached a new understanding of the issue involved: the officials were replacing physicians as “experts” in the area.

“...HMOs delegate this power of decision making to professionals...they should prove first that the **product** is effective...and second that it should benefit the HMO” (Interviewee I, EX).

The next interviews ratified this concept. There was a change of focus for the pharmaceutical company; from the ambit of the physician to the official. This change was motivated by a transfer in the decision making process. It was no longer the physician who decided what to prescribe but the official who indicated to the physician what to prescribe.

“The company’s customer changes from being exclusively the physician to be a combination between the physicians and the HMOs who are responsible for the reimbursement of the drug. HMOs are deciding what the physician prescribes, narrowing the prescription alternatives in the formularies” (Interviewee B, PH).

“Research on who is responsible for the incorporation of a **product** in the formulary is the initial step; is he the auditor or the medical practices manager?” (Interviewee A, PH).

The pharmaceutical industry previously promoted the drugs to the physician alone and

the physician had the authority to prescribe what was best for the patient. If the patient complied with the physician's prescription, he/she purchased the pharmaceutical **product**. The person with the knowledge to diagnose the right disease and to indicate the right medicine was the physician. The pharmaceutical companies had no influence in patients regarding medicines which need a prescription. It was illegal for pharmaceutical companies to promote these medicines which need prescription directly to the patient. The physician was the individual who had the power to decide what was the best drug for the patient. Pharmaceutical companies promoted the medicines that needed a prescription only to physicians. This was the classical industry-physician-patient relationship. Respondents mentioned that with the introduction of restricted formularies the physician lost his/her freedom to prescribe. A closed formulary is a restricted list of **products** that limits reimbursement to specific products: the list is given to physicians and pharmacists to guide them in the prescribing and dispensing of pharmaceutical **products**. Physicians were compelled to prescribe the **products** that were in the formulary even if there was a better alternative for the patient. The official took the role of expert and decided which **products** should be included in the formularies. There was a transfer of power of decision making from the physician to the official. The physician diagnosed the disease but he/she is no longer decided what to prescribe- the official now took that decision.

“...the official issues strict rules to the physicians; when the physician works in a clinic with an internal pharmacy, the official tells the pharmacist to replace **products** for the ones in the formulary. Officials exclude on purpose some **products** from the formulary...” (Interviewee B, PH).

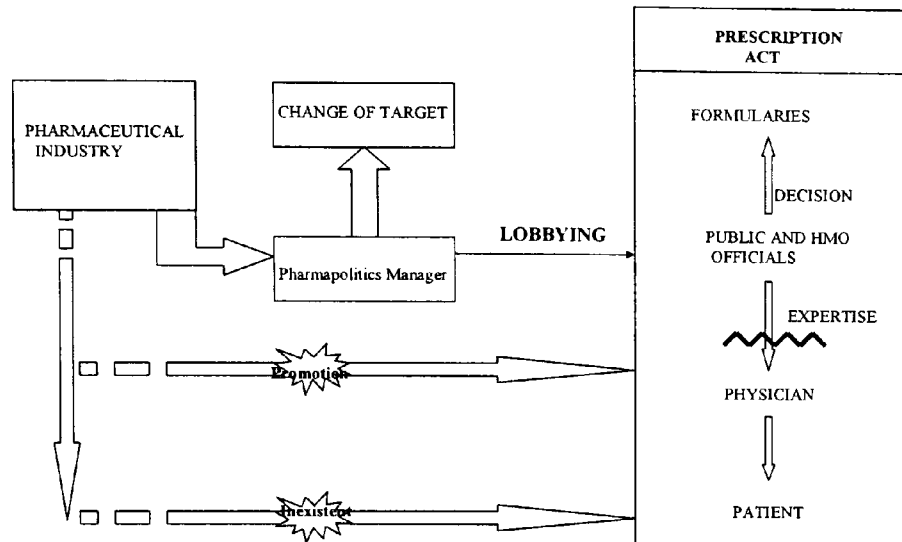
The pharmaceutical industry, through its pharmacopolitics managers, changed its habits because of this situation: still promoting to physicians but lobbying the officials for the

introduction of new **products** in the formularies. The physician lost his/her role as an expert and the official now occupied this role.

“There is no doubt about it. It is one of the few transactions where the consumer does not decide- the physician decides for the patient. On another level, somebody who could even not be an expert in the field (the official) decides whether a physician should or should not prescribe a certain **product**, even not knowing what the **product** is about...”
(Interviewee C, PH).

The introduction of **products** into formularies was one of the main lobbying activities of the pharmapolitics manager and this was always present in the data. Thus the researcher developed a tentative model of this transfer of decision making power from physicians to officials in relation to the introduction of **products** onto formularies. This model illustrated the concept of the transfer of decision making power from physicians to officials. The model was validated and saturated during the interviews. The interviews helped to expand the model and the sub-category. As a result, the researcher identified a new sub-category- “**target for lobbying**”- which seemed to explain not why companies lobbied but why they chose officials as the **target for lobbying**. They chose officials because they were responsible for the formularies and the introduction of **products** onto formularies was one of the key aspects of the pharmaceutical companies’ lobbying interests. The model shows the different aspects of this transfer of decision making power.

Figure 4 *Model of transfer of decision making power*



The pharmaceutical industry, through its pharmapolitics managers, changed **target** and decided to lobby the public and HMOs officials. The relationship between the official, the expert now, and the physician and the patient had been broken. The official had the power to decide what was included in the formularies and frequently, but not always, the knowledge to decide what was the most cost-effective treatment for the HMO. The **target for lobbying** was now the official.

Respondents also mentioned that the **target for lobbying** should be at the highest possible level in the officials' hierarchy. The pharmacopolitics manager's objective was to lobby the highest-ranking officials as they are the ones who actually made the decisions. The reason why the highest ranking official was the **target for lobby** was explained by the following quotations:

“My personal **strategy** is to approach the superintendent directly, considering his status as a physician. I begin with him, at the head of the organisation, as he gives directions and so that the subordinates will hear us...” (Interviewee B, PH).

“Why begin at the head of the organisation? Because if you begin at the head of the hierarchy and he give orders to his subordinates, the process is much simpler. When the head says: ‘go and see this x official and explain the same that you have explained to me’ and then you go and see this official, this official has already received the call from the head who told him ‘have an interview with this pharmapolitics manager. He is going to explain something to you that sounds interesting to me’. After that you don’t have to do much more...” (Interviewee A, PH).

The “**target for lobbying**” represented the platform on which all the lobbying process was based. Pharmapolitics managers identified the **target** as the public and HMOs officials, separating themselves from the classic approach of the pharmaceutical industry namely influencing only the physicians. A transfer of decision making power took place and the official now occupied the “expert” role deciding on health care issues. The pharmapolitics manager **strategy** was to lobby the highest-ranking officials as they were the ones who decided on health care matters.

*Question two and three (Sub-Category = **Motivations**)*

What do you think are the key motivations for pharmaceutical companies to lobby public and HMO officials?

What are the objectives that you seek when you lobby officials?

Once the **target for lobbying** was identified, the researcher’s next objective was to decipher what were the **motivations** of the pharmaceutical industry in lobbying the officials. As mentioned previously, the researcher used both questions to collect the

information from two different perspectives: the strategic one (motivations) and the tactical (objectives). The researcher decided to use the term **motivations** for the sub-category including both perspectives. For the study, **motivations** referred to the reasons why pharmaceutical companies lobbied officials what is related to the first research question: “Why does the pharmaceutical industry lobby officials?”

Analysing the open coding, the researcher realised that most of the labels were activities e.g. *introducing* products, *increasing* market share, *influencing* officials, etc. but there was no process to be analysed but concepts implied by those activities. The researcher re-grouped those activities into concepts that reflected the pharmaceutical companies’ **motivations** to lobby officials. The **motivation** concepts that arose from the data were: introduce products in the formularies, maintain market share and increase sales and profits. By reviewing the transcripts and by reflecting on the interpretations of what the respondents had said, the researcher realised that there were implicit activities that were present in the data. The researcher open coded these activities and re-grouped them into two new **motivation** concepts: simplify future negotiations and influence official decisions. The following table depicts the five concepts:

Table 14 *Motivations concepts*

| |
|--|
| <i>Motivations</i> |
| Introduce products in formularies |
| Maintain market share |
| Increase sales and profits |
| Influence decisions |
| Simplify negotiations |

These concepts reflected the reasons why the pharmaceutical companies and the pharmacopolitics managers carried out lobbying to officials. The five concepts through the process of axial coding were integrated in the sub-category **motivations**. The substantive theory around the concepts will be explained next.

Introduce products in formularies

This concept was the most prevalent in the interviews. The first **motivation** for lobbying officials was to introduce new **products** in the formularies. The pharmacopolitics managers highlighted it as one of the most important activities of their job.

“...to achieve the objective that is to have the **product** included...” (Interviewee A, PH).

“...the work of lobbying is based in providing scientific information and at a certain point negotiating the incorporation of one **product**...” (Interviewee A, PH).

“...if the question is: why lobby? The answer is a little bit different. It relates to the issue that, in Argentina, not all HMOs or state institutions accept that all **products** of all pharmaceutical companies should be included in the formularies. Therefore, the pharmaceutical company has to get close to these institutions in order to explain its motives and the reason why its **products** should be in the formulary of the HMO or institution” (Interviewee B, PH).

Pharmacopolitics managers focused all their attention on introducing the **products** into the formularies. They did not mention why it was important for the company to introduce the **product** in the formularies. Reflecting on this issue, the researcher realised that pharmacopolitics managers took for granted the explanation of why introducing a **product**

in a formulary was important. Only one respondent, a free-lance lobbyist, explained why the introduction of new **products** in formularies was important:

“The reason why formularies are important is because they state which **products** should be prescribed by the physicians and reimbursed by the HMO. In the case where an HMO has three million affiliates, like PAMI (pensioners HMO), and a certain **product** from my company is not included in PAMI’s formulary, those patients cannot buy my **product** because this **product** has no reimbursement for them and they have to pay full price. If the number of people in Argentina with health care coverage is twenty four million people, not having a **product** in PAMI’s formulary means that my **product** can only be bought by twenty one million people in the best case. When a company introduces a new **product** in the market, there are only three and a half million who can buy the **product** if they are affiliated to an HMO with an open formulary; that means that they have reimbursement for the new **product**. It is essential for the pharmaceutical company to broaden its market by introducing the new **product** in the formularies...” (Interviewee L, EX).

The researcher noticed that pharmapolitics managers in the first three initial interviews did not spontaneously mention the link of introduction of new **products** in formularies and the increase in these **products’** sales. The researcher probed this concept in the following interviews and received responses like:

“...my job is to have the **products** introduced. I am not responsible for the new **product** sales...” (Interviewee E, PH).

“I get my annual bonus from the degree of penetration in the formularies; it is not related to sales...” (Interviewee G, PH).

The perspective of the pharmapolitics manager was only to lobby the officials to include

the **products** in the formulary- their performance was not related to sales of the **product**. The researcher noted that the sales directors interviewed spontaneously mentioned incremental sales. They said that the introduction of a **product** in the formularies “leverages the sales of this **product**” (Interviewee S, SD).

“...as in every place, the first **motivation** is the introduction of the company’s **products**. That means, to sell its **products**. The **motivation** is this one. The most desired interest of the pharmaceutical company is good profit and good profit begins with the sale of its **products**. The **motivation** to lobby is to sell the company’s **products**” (Interviewee V, SD).

This link to increasing sales was described by HMO officials from a negative perspective:

“...a new introduction increases my costs...” (Interviewee N, HO).

“...have already negotiated a discounted price, at least for two or three years, in the case of chronic illness **products** because the new **product** is a burden in our HMO costs...” (Interviewee O, HO).

Two respondents also mentioned that the introduction of a **product** in a certain HMO like PAMI, the pensioners HMO, was a positive marketing action. PAMI was the biggest HMO in Argentina and the inclusion of a **product** in PAMI was essential for the success of a new **product** in the market. There was a domino effect towards the other HMOs after the inclusion of a **product** in PAMI.

“When this reality is explained to a manager who comes from abroad, it is not easy for him to understand that his company pays a very high rebate to be in PAMI’s formulary.

We consider that PAMI is a great shop window, a great marketing trigger for the **product**” (Interviewee F, PH).

One respondent mentioned that it was necessary to overcome the entry barriers imposed by the competitors to achieve a better position in the formulary. The researcher found that this assertion was related to the formularies in which the drug is already included and one pharmaceutical company looked to introduce its own trade-mark.

“If I cannot get my **products** in the formularies it is because my competitors are protected by some sort of prebends that I have not implemented. I have in some way to disarticulate this situation to get my **products** in” (Interviewee B, PH).

Maintain Market Share.

Respondents considered that one **motivation** to lobby the officials was to maintain market share in the HMOs that have formularies. Officials periodically introduced new **products** but they also took out **products** based on lack of efficacy or costs. This issue was critical for pharmapolitics managers whose job was not only to introduce new **products** but also to maintain the **products** already introduced. This concept was supported by respondents:

“...not to lose the opportunity to secure formulary positions in an HMO...to avoid being excluded from the formulary...” (Interviewee A, PH).

“...to promote the **product** and extend its use in other HMOs using the fact that it has been introduced in this HMO...” (Interviewee F, PH).

This sub-category was firmly supported by all respondents as it was seen as essential to maintain competitive position in the formularies: older **products** should have the same chance as new **products** to be prescribed and reimbursed.

Increase sales and profits

The researcher realised during the interviews that there was, in the language of the pharmapolitics manager, a division between sales that originated from the introduction of **products** in formularies and those sales that originated from direct lobbying of HMOs or the government. The difference was that direct lobbying could achieve additional sales from the government or from HMOs in the cases of chronic illness. These direct sales were directly to the health care provider and they do not derive from formularies. This **motivation** of incremental sales and profits was one of the **motivations** of the pharmapolitics manager in their approach to officials.

Three pharmapolitics managers referred to their task as also lobbying HMOs in order to sell their **products** in disease management programmes at good prices. These programmes targeted chronic illness. The HMO provided the medication directly to the patient without the intervention of a pharmacy.

“HMOs manage disease management programmes as chronic illnesses or a catastrophic disease...the lobbying is to sell these **products** to HMOs at a good price” (Interviewee B, PH).

“**Products** related to special treatments have a different approach, more based in the commercial side. One looks for the best commercial agreement for the HMO and for the pharmaceutical company” (Interviewee A, PH).

“...there is a reimbursement from the APE (government) to the HMOs, so that you can negotiate a better price” (Interviewee C, PH).

Another **motivation** to lobby was the possibility of selling directly to HMOs without going through a tender process. These sales usually entailed a better price as there was

no competition from other companies.

“...the equation should be profitable for the company...” (Interviewee D, PH).

“...more focused in analysing the fine details of the business than in purchasing the cheapest **products** which are against the quality of health care for their patients” (Interviewee I, EX).

Two pharmacopolitics managers commented that another **motivation** was to “lobby to achieve certain type of sales to the government” (Interviewee A, PH) regarding tenders of new **products**. The government had to purchase pharmaceutical **products** through a tender process. The pharmacopolitics managers’ job was to lobby to have the new **product** included in the tender process.

“...to position a **product** in the tender when the government is developing a coverage plan for a specific pathology” (Interviewee G, PH).

“It could also be lobbying to achieve sales to the government, in some coverage plans, when the government buys drugs” (Interviewee A, PH).

On reflection, the researcher realised that the officials who developed formularies were also involved in the implementation of the tender process. The pharmapolitics manager had the same interlocutor - the government official or the HMO official. This finding explained why the pharmapolitics manager, and not the sales representative, was responsible for sales. The pharmapolitics manager had an established relationship with the official that positioned himself/herself better to include the company’s **product** in the tender.

Influence decisions

The three concepts are explicit **motivations** for lobbying. By reviewing the transcripts and by reflecting on the interpretations of what the respondents had said, the researcher realised that there were implicit activities that were present in the data. In all interviews with pharmapolitics managers, the researcher realised there was actually a stronger **motivation** than the explicit **motivations** mentioned. The researcher had to interpret phrases and activities hidden between explicit **motivations**. The researcher open coded these activities and re-grouped them into a new **motivation** concept. The explicit **motivations** were the reasons of the company but the pharmapolitics manager's most strongly supported **motivation** was to be able to exert influence on the official. After identifying this **motivation** the researcher went through the data and found that this **motivation**, was present in all the pharmapolitics interviews. Some examples showed this **motivation**. The possibility of influencing, or the influence exerted, is underlined:

"...there is always the possibility of modification of a law in Parliament..."
(Interviewee A, PH).

"...the adequate lobby could even make an official turn away the scientific matters..."
(Interviewee J, EX).

"Changes like that were achieved; not very easy...but through meetings with the Minister of Health, the regulation was changed..." (Interviewee B, PH).

The researcher considered that the **motivation** to exert influence on officials' decisions was one of the most important for the pharmapolitics manager. The pharmapolitics manager's job was to lobby the official and thus influence that official's decision. The researcher found out that there was a confluence between the **motivation** and the job, as if there was an overlapping of work required and desire to do it. The pharmapolitics

manager needed to be able to influence the official decisions. As mentioned previously in the motivation concept “Introduce the product in the formularies”, pharmapolitics managers focused all their attention on introducing the **products** into the formularies and did not mention why it was important for the company to introduce the **product** in the formularies; introducing a product in a formulary is a way to exert influence on the official. The **motivation** was for pharmacopolitics managers to exert influence, not to sell the companies’ **products**. The last three interviews with pharmapolitics managers (who were re-interviewed) confirmed this proposition.

“... conclusively there is a **motivation** to have the legislation changed. I believe lobbyists in the entire world do just the same. An example could be to lobby in congress (deputies and senators), provincial parliaments or Buenos Aires Town Hall to make evident that it would be convenient (from the perspective of the pharmaceutical company) that a certain law should be modified for the welfare of the entire population” (Interviewee B, PH).

Simplify negotiations

This concept related to the sub-category of **building trust**. Initially the researcher included this **motivation** in the **building trust** sub-category but later in the research process realised that it should be included as another **motivation** concept. The respondents mentioned that the fact of always lobbying with the same officials created an environment of trust, which might simplify future negotiations.

“...it is essential to establish and maintain the relationship and give to it some added value like collaborating in the layout of a pathology program, helping in an emergency situation with the free provision of a drug...consequently the negotiations are much simpler” (Interviewee A, PH).

Pharmapolitics managers used lobbying as a tool to create a working relationship in the future. The outcome of lobbying could be negative in the present but it would help in future meetings between the pharmapolitics managers and officials. The action/interaction of the **participants** of the lobbying process modified the context towards a positive attitude in future negotiations.

*Question four (Sub-Category = **Participants**)*

*Who are the **participants** in the process of pharmaceutical lobbying?*

The **participants** in the process of lobbying relates to the basic question: “**Who**” lobbied officials? After the open coding, the researcher identified nine different **participants** in the lobbying process. The degree of participation in the lobbying process was a property which helped the researcher to classify the participants. Taking this degree of participation as a parameter, the researcher classified them as active **participants**, passive **participants** and occasional **participants**. The following table shows the different **participants** in the lobbying process.

Table 15 *Participants in the lobbying process*

| <u>Active Participants</u> | <u>Passive Participants</u> | <u>Occasional Participants</u> |
|-----------------------------------|------------------------------------|---------------------------------------|
| Pharmapolitics Managers | Pharmaceutical Companies | Chamber (CAEMe) |
| Public Officials | Government | American Embassy |
| HMOs Officials | HMOs | Free-lance Lobbyists |

Active Participants

The Pharmapolitics managers were the proactive **participants** of the lobbying process. They were the initiators of the lobbying activities towards officials, trying to influence the decisions of the officials. They were also the initiators of the process of lobbying in pharmaceutical companies.

“...those responsible for pharmapolitics try to work with the needs of the government officials...” (Interviewee D, PH).

“...the good work of pharmapolitics managers could even produce a turn away from science in the mind of officials ...talking about trade union HMOs and private HMOs, the introduction of a **product** is based on good lobbying and not on the scientific information...” (Interviewee A, PH).

The officials, as the objects of the lobbying, had to decide whether to accede to the petition of the pharmapolitics manager or not. They had to decide whether to grant the pharmapolitics managers access.

“...the **participants**, from the government or HMOs, are the same (officials)...” (Interviewee B, PH).

“...regarding the informal procedures, one tries to get as close as possible to the people who take the main decisions...” (Interviewee D, PH).

“...frequently, it is the official who proposes a different agreement for the introduction of a **product**...” (Interviewee A, PH).

Usually the lobbying process was conducted between the pharmapolitics manager and

officials. Various interests influenced the decisions taken by officials, frequently not related to scientific or medical matters but to other aspects of the relationship existent between the official and the pharmapolitics manager.

“...surely there is an economic issue behind this. And the economic issue in Argentina could mean two things: the first that there is an important benefit for the institution (HMO)... the second possibility is that there is a personal interest...” (Interviewee B, PH).

“An alarm signal is when the process stops without an apparent cause. This implies that the motivations are other factors but not scientific ones...” (Interviewee E, PH).

The official was the individual who, through the establishment of close ties with the pharmapolitics manager, was responsible for expressing both the needs of the HMO and him/herself. The pharmapolitics manager usually worked on them to have a **product** introduced in the HMO's formulary.

“...work over the needs of the HMO, whether it is software, scientific evidence, or the training of the personnel. He should also identify if the official has personal needs...” (Interviewee H, PH).

Pharmacy Benefits Management Organisations exist in Argentina and they played a role in the creation of formularies. The researcher noticed that respondent's attitude to them was the same as to HMOs and so for the purpose of this study they have been referred to as HMOs.

Passive Participants

The passive **participants** were those entities who gave the active **participants** assignments. The pharmaceutical companies sent the pharmapolitics manager to lobby

the officials in order to be able to influence decisions in the HMOs or in government.

“...corporatism requires that pharmaceutical companies, and especially their pharmapolitics managers, participate in corporate lobbying activities...” (Interviewee K, EX).

“...these new pharmapolitics managers are not related to the old managers, or sales managers, whose task was to convince the physicians about the therapeutic qualities of a **product** or to train and motivate the sales representatives to achieve this objective. Today, this manager is a highly skilled negotiator who has to deal with the representative of the HMO who is another negotiator with opposed interests to that of the pharmaceutical company”. (Interviewee J, EX).

On the other side, the government and HMOs gave the officials delegated powers to implement formularies that could affect the interest of the pharmaceutical companies. Officials converted themselves into the **target** for pharmaceutical lobbying.

“...these types of institution (HMOs and government) delegated the decision making power, or at least this possibility, to professionals (officials)...” (Interviewee S, SD).

“If the responsibility of the decision, or the power to decide, lies exclusively in a professional (official), I would get in contact with this professional...” (Interviewee I, EX).

“The fundamental issue in all cases is to discern who the person is that takes the decision...” (Interviewee A, PH).

Occasional Participants

Occasional **participants** were those that sometimes facilitated the lobbying of the

pharmapolitics managers. In this research three types were identified. The first one was the Multinational Companies Chamber (CAEMe). The chamber itself negotiated some HMOs formularies.

“...the Chamber has to represent the interests of all companies...” (Interviewee A, PH).

“...in the decisions that are taken in congress or in the health superintendence, I believe that the Chambers have a great influence” (Interviewee B, PH).

The second was the American Embassy. It was a strong negotiator at the time of the issuing of the Patent Law and its modifications. PhRMA, the American Pharmaceutical Chamber, also pressured the American Embassy to push for changes in the Patent Law.

“...due to the pressure of the American Embassy on the Government, a great change was achieved in the Patent Law...” (Interviewee U, PO).

Free-lance lobbyists were used also in the lobbying of officials. In the cases where the pharmapolitics manager had no access to a specific official, or the pharmapolitics manager lobby had failed, free-lance lobbyists were hired.

“...when the lobbying has no effect, one looks for alternative ways to achieve the goal...” (Interviewee D, PH).

One respondent mentioned that free-lance lobbyists were hired when the company's compliance rules prevented them from meeting the official's requests.

“If the official requested direct payments, we would rather hire an external lobbyist to do the job...” (Interviewee F, PH).

*Question five (Sub-Categories = **Product – Building Trust**)*

What do you think are the key issues for success when you engage in lobbying?

The respondents expressed many different issues for success in the lobbying process. At first sight, the researcher thought that it was going to be difficult to build substantive theory with this dispersion of data. The researcher performed the open coding and labelled the data. Concepts, sub- concepts and activities emerged. After the first coding, the researcher began to look for relationship between the sub-concepts, concepts and activities looking to integrating them in a broader concept. At that stage he could identify two perspectives; there were concepts related to the product and its characteristics and there were concepts referred to the relationship with the official.

One key issue was the existence of a scientific **product**, in this case the pharmaceutical **product**. For effective lobbying, the pharmapolitics manager needed a physical **product** with certain and specific properties. Responses such as need of information, scientific support and scientific evidence related to the existence of a **product** with specific properties. The researcher identified that they were talking about the properties of the **product** that they were supposed to lobby. The basic research question “what” came out after the open coding process, from the data itself, as the question as such was not present in the fixed set of questions.

On the other side, all respondents mentioned that **building trust** with the officials was essential for any lobbying activity. The **building trust** process should begin before any lobbying was carried out.

The researcher established that the key to success of the lobbying were these two issues. After the open and axial coding the researcher integrated all the responses in two sub-categories named **product** and **building trust**.

The researcher explains first the findings related to **product** and then to **building trust**.

Product

The lobbying was based on the pharmaceutical **products** of the companies, which were the material object or objects; that meant the different items that the companies researched, developed and later introduced in the market. Pharmaceutical **products** have different properties themselves but in the context of pharmaceutical lobbying, respondents emphasised specific ones. The researcher classified those properties as two types: intrinsic and perceived.

Intrinsic properties

Respondents commented about the special characteristics that pharmaceutical **products** needed in order to be successful in the context of lobbying. The intrinsic properties of the **product** could be further broken down into the following areas: quality, scientific support, essential for the patients and broadly used.

Pharmapolitics managers emphasised *quality* as the difference between multinational companies and generic companies. Officials had the same valuation of quality. Quality was important for pharmapolitics managers as they needed to be sure that the **product** would be effective when it was used by the physician. They lobbied officials in the knowledge that the **product** had a certain efficacy and safety profile and that the official believed in what the company said. The situation was different in the case of generic companies, where the **product** had to be tested on patients to validate the efficacy.

“Inevitably they (officials) should try to generate fair rules for the **participants** and deter price competition with players who do not have adequate quality standards...”
(Interviewee J,EX).

“...to have an extraordinary **product** is reason enough to be included in a formulary...”

(Interviewee B, PH).

All respondents mentioned *scientific support* as one of the most important property for lobbying success. Scientific support represented all the information about a **product** such as clinical trials in animals and humans and the results of these trials. Officials also expected the pharmaceutical company to present scientific evidence of the efficacy of a **product**.

“...present the **product** that has enough scientific evidence although sometimes the official does not consider all the scientific material available in the dossier...”

(Interviewee A, PH).

“...I have to use the back-up of knowledge: literature, clinical trials, etc. I have to get all this to persuade a professional (official)...” (Interviewee F, PH).

“...this requires that previous data exists...to demonstrate that the item is cost-effective compared to other alternatives; that there is a benefit from the pharmacological point of view and a benefit from the cost of the drug. This demonstration should be done from the scientific and economic side”. (Interviewee D, PH).

Essential for the patients: Pharmaceutical **products** were essential for the health of the patients. This quality was more relevant to officials than to pharmapolitics managers. Officials expected that new **products** would have substantial improvements compared to the existing ones, improving the prognosis of the disease. Officials mentioned that in recent years the pharmaceutical companies have been launching me-too **products** (products with a similar chemical structure but with no therapeutic advantages over the ones already in the market) with a higher price and they regarded those **products** as expensive and not cost-effective. These types of products were not regarded as essential

for the patients and they should not be introduced in the formularies.

“The motivation lies in the welfare of the patient; the government has a function of being the controller of the health system and it should try to foster the new advances in therapeutics” (Interviewee R, PO).

“...a new **product** substitutes other **products** and not only that but it substitutes other therapies. That the new **product** avoids hospitalisations and makes the patient's life better” (Interviewee C, PH).

Broadly used: Pharmapolitics managers knew that one property for lobbying success and the introduction of the **product** in the formularies was that it was usable by a large group of patients. The **product** itself should have quality, scientific evidence and be essential for the patients. Officials felt pressured to introduce it because the new **product** would benefit a large number of patients. Nevertheless, officials tried to restrain the utilisation of new drugs because of cost-containment within the HMO.

“HMOs, with excellent service and managed by very bright people, prefer to pay more in the future for the effects of illnesses rather than to pay now a significant sum for a **product** which could save future costs”. (Interviewee B, PH).

Perceived properties

These were the properties that the officials and the pharmapolitics managers viewed in the pharmaceutical **product**. It entailed how the participants expressed their views about the material object - the pharmaceutical **product**. These properties were vital in the context of lobbying to understanding the preconceived conceptions that officials and pharmapolitics managers had in the lobbying process. These properties are scientific value, economic value and social value of the pharmaceutical **product**.

Pharmapolitics managers believed that the companies' **product** had an adequate scientific value that made possible the lobbying process. In other words it was thoroughly researched and tested and that there was sufficient scientific information to be presented to the official for the inclusion in the formulary. This belief was shared by the officials who considered the pharmaceutical **products** to be of high scientific value. There was a consensus between the official and the pharmapolitics manager that the **product** had a proper scientific status.

"...present scientific evidence, pharmaeconomics studies..." (Interviewee E, PH).

"...in catastrophic diseases...there are **products** with excellent scientific support and they are unique for the disease..." (Interviewee M, HO).

"This demonstration has to be done from the scientific perspective..." (Interviewee O, HO).

Due to its scientific value, the respondents believed that it should be the official who decided about its utilisation. The official prevailed over the physician in deciding which **products** should be prescribed. Pharmapolitics managers mentioned this issue as prevalent over others.

"It is one of the few transactions in which the consumer does not decide, but the physician decides for him. On another level, somebody (official) who is an expert in the subject should decide whether a physician can prescribe a **product** or not" (Interviewee C, PH).

The economic value property was controversial. The perspective was different depending whether the respondent was an official or a pharmapolitics manager. For the pharmapolitics managers the economic value of a **product** was the highest percentage

of reimbursement for the patient or the highest price. The highest percentage of reimbursement facilitated the patient the access to the medication. The pharmapolitics managers perceived the highest price as being a result of introducing new **products** in disease management programs. Recently launched products were not normally suggested as possible entries on the formulary lists.

“I must achieve the highest percentage of reimbursement in PAMI (pensioner’s HMO) as there are thousands of patients who can buy my **product**” (Interviewee F, PH).

“...disease management programmes for chronic illnesses or catastrophic diseases; the lobbying is carried out to sell at a good price...” (Interviewee B, PH).

Officials, on the other hand, perceived new **products** as a cost burden for the HMOs. The cost containment policy implemented by HMOs restrained the official’s ability to easily incorporate new therapies.

“...the majority of HMOs based their decisions on economics, where price matters...” (Interviewee H, PH).

“...in HMOs there is a rationalisation of cost in medicines. Restricted formularies are a way to contain costs in medicines...” (Interviewee M, HO).

For officials the new **products** were more expensive and had no additional advantage to the ones in the formularies; these **products** were regarded as not being cost-effective compared to the current alternatives to treat the disease.

“Today you should prove to the officials the advantages of the introduction of a new **product** in the formulary; even the economic advantages of your **product** versus that of your competitor” (Interviewee J, EX).

Respondents also mentioned that the economic value of a **product** could be a definitive argument to achieve the incorporation of the **product** in the formulary. That meant to show that the **product** was cost-effective in pharma-economic terms.

“If they (the **products**) do not have enough comparative advantages over the **products** already in the formulary, I would try to work on the economic side and costs...”
(Interviewee A, PH).

Pharmapolitics managers expressed that there was a social value of the **product**, meaning that the pharmaceutical **products** provided the patients a better life or a longer life expectancy. This quality was related to some new **products** that gave a better therapeutic alternative than the ones already on the market. Its use gave the patient a better life. The officials perceived social value as a pressure to include the **product** in the formularies. Officials aimed at improving the quality of life of patients by providing health care and when a **product** presented a benefit for the patient they should include it in the formulary. Pharmapolitics managers were aware of this objective and they used the social value as a tool to pressure the official. A pharmapolitics manager viewed the issue as follows:

“It is a **product** with a high social sensitivity and the construction of a social framework is essential to the pharmaceutical companies business...” (Interviewee J, EX).

“...there is a vision of medicines as a social good with subsidies from the government...” (Interviewee D, PH).

The first sub-category was the existence of the material object namely the pharmaceutical **product**. The second one was **building trust** with the officials.

Building trust

This sub-category was mainly concerned with the issue of building relationships between the pharmapolitics managers and officials. Respondents stated that **building trust** was one of the key issues for the pharmaceutical lobbying process.

“...the pharmaceutical companies’ closeness with the state and trade union HMOs is essential for getting to know the key people and to be known by them” (Interviewee B, PH).

Respondents mentioned that no effective lobbying could take place without an established relationship, which permitted the creation of a negotiation environment that allowed the presentation of the request of the pharmapolitics manager. It also permitted the expression of the officials’ interests, needs and demands.

“Lobbying has to do with a deep relationship. This relationship goes beyond the lobbying process company-HMO and company-government...” (Interviewee A, PH).

“The **participants**, in the government and the HMOs, are always the same people. You build a relationship, a friendship...” (Interviewee D, PH).

The researcher identified two different concepts in the **building trust** sub-category. The first was the need for pharmapolitics managers to build a long-term relationship with the officials independent of a special lobbying need. The second was the creation of a negotiation environment for a specific lobbying process.

Building relationships.

Pharmapolitics managers emphasised the fact that building relationships with the HMO and public officials was vital for lobbying success. Respondents said that the

relationship with key officials should be established and maintained in time so that it could be used when needed.

“...it is essential to establish the relationship, maintain it and provide some added value to it...” (Interviewee A, PH).

This relationship was independent of whether there was a specific interest at that moment.

“...the relationship is most of the times beyond the lobbying of pharmaceutical company-HMOs or pharmaceutical company-government...” (Interviewee F, PH).

There was special focus in the personal side of the relationship so that the formal relationship became a close one, where the pharmapolitics manager and the official interacted.

“You get a close contact, and that is where a friendship begins...” (Interviewee A, PH).

“...one tries to position the company’s **product** based on the relationship that one has with the official...” (Interviewee C, PH).

Pharmapolitics managers focused on the personal interests of the officials in order to get close to them and to be able to build an environment of trust.

“The personal aspects should never be left aside because the Formularies Committees are composed of people and those people are the ones who take the ultimate decision...” (Interviewee D, PH).

The aim of the pharmapolitics manager was to establish those relationships with the highest-ranking officials in order to effectively influence the HMO or the government. These relationships could simplify present and future negotiations.

“...if you begin with the head, there are fewer steps that you have to follow. If you persuade the head, seventy-five percent of the decision is made. If you begin with middle management it is more difficult...” (Interviewee B, PH).

“...regarding the informal processes, your aim should be to get as close as possible to the key decision people”. (Interviewee D, PH).

Consequently, the fundamental properties of this concept were:

- a) Essential: lobbying for pharmapolitics managers was quite difficult without the building of the relationship.
- b) Highest ranking of officials: the pharmapolitics manager focused his/her lobbying activities on the key decision makers.
- c) Personal: not based on formal contacts but on the informal ones. Officials and pharmapolitics managers built personal ties between them.
- d) Stable in time: the relationship continued over time and became stronger through years of interaction.

The building of a close, informal, long-term relationship with officials provided the basis to build a negotiation environment for the lobbying process.

Negotiation environment.

Respondents said that the meaning of a negotiation environment was a time and place where the officials were confident in discussing certain issues, for example the introduction of a new **product** in the formulary.

“Then the negotiation begins, there, in this moment when one can bring an alternative solution to the issue...” (Interviewee A, PH).

Respondents separated the relationship and the negotiation environment. The close relationship achieved generated the environment but the responses clearly highlighted the differences:

“...through pharmacopolitics it is necessary to achieve a space, a place, from where one can present the advantages of the **product**...” (Interviewee C, PH).

According to interviewees, the environment was created in response to a specific need and it was built before the process of lobbying began:

“...the early construction of this negotiation environment is a substantial part of the lobbying business of the pharmaceutical companies...” (Interviewee J, EX).

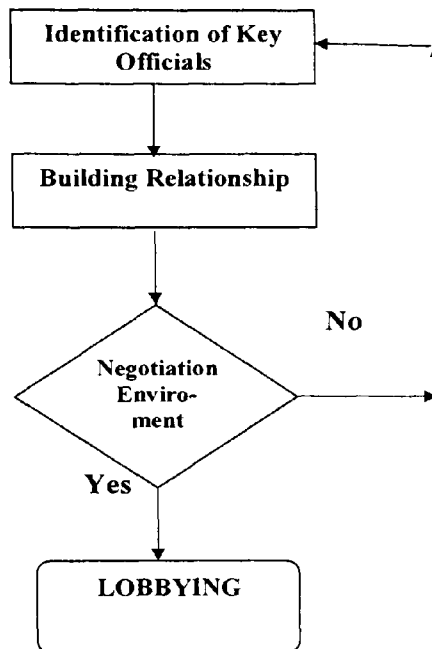
“...it is necessary to choose well the place where you are going to meet the official. He should be relaxed and comfortable. When I realised that he was in good mood, I would begin to talk about my **product**...” (Interviewee H, PH).

The researcher took these two concepts, building relationships and the negotiation environment and analysed the open coding from the perspective of the processes and sub-processes. He realised that building trust was itself a process so that he analysed the sequences of evolving actions/interactions and he developed a model of the **building trust** process. The researcher identified the main sub-processes which were the basis for the model. The researcher used coding for process to illustrate the **building trust** process. The diagram below depicts the process before the specific process of lobbying began. The pharmacopolitics managers stated that they first looked for key officials with whom to build a long-term relationship. Once identified, they began to build a close

relationship. No respondent clarified in which way they built the relationship. The researcher noted that the interviewees used all means of hospitality. This brought out the issue of reciprocity. Reciprocity means that in response to friendly actions, people were frequently much nicer and much more cooperative than predicted (Fehr & Gächter, 2000). Knack (2000) remarked that when trust and norms of reciprocity were stronger, opposing sides were more likely to agree on the ground rules for seeking debate. Butin et al (2005) described three major aspects that must be fulfilled in order to denote actions or situations as reciprocal: a) a sequential process within which an individual acts b) another reacts and the reacting individual can grasp the effects of the first action and c) the second individual aims at creating a kind of equality or parity (tit-for-tat). Axelrod (1984) showed how stable cooperative behaviour could arise in self-interested agents when they adopt a reciprocal attitude towards each other. Susman (2006) referred to reciprocity in American congress; he remarked that lobbyists provided gifts and entertainment to the legislators to obtain preferential treatment. He concluded that, in spite of all the lobbying regulation in the USA, nobody had addressed the basic human impulse to return a favour. The data from the interviews provided no support to the theory that the relationships and the building trust process were built under a positive reciprocity relationship. Even then, participant observation showed that all means of hospitality were used- meals, tickets, etc- and this indicated an implicit reciprocity process.

Once the relationship was established, pharmapolitics managers tried to build the negotiation environment for a specific issue. The building of the negotiation environment enabled lobbying to take place. In cases where it was not built, the pharmapolitics manager had to strengthen the relationship in order to develop the negotiation environment.

Figure 5 Building Trust Model



After building the negotiation environment, the lobbying process began. The researcher implemented the following questions for the gathering of data on the lobbying process.

*Questions six, seven, eight, nine, ten (Sub-Category = **Strategy**)*

How would you describe the process of pharmaceutical lobbying?

*Which **strategy** do you follow if you want to influence an official?*

How much relevance do you give to scientific information in the process of lobbying?

Are there other non-scientific instruments that you use to achieve your objective?

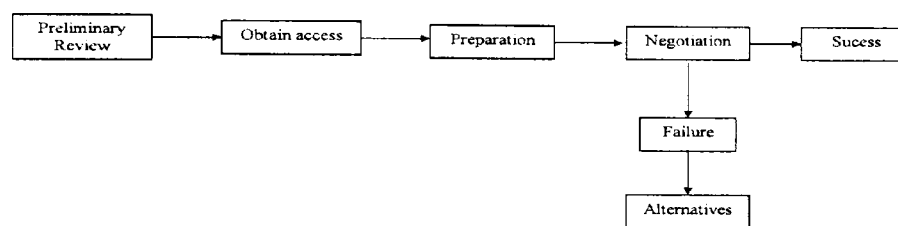
When a lobbying process is not successful, what do you do next?

Strategy was the most relevant of all sub-categories. This sub-category described how lobbying was performed by the pharmapolitics managers. The findings related to the second research question; how lobbying was carried out by pharmapolitics managers. Within this sub-category the *pharmaceutical lobbying process* was explained.

Pharmaceutical lobbying process

The researcher used coding for process for the analysis of this concept. This coding looked at the different activities that were included in the lobbying process. The researcher identified five sub-processes: preliminary review, obtaining access, preparation, negotiation and results. Below is a chronological description of the five sub-processes:

Figure 6 *Lobbying process model*



Preliminary Review:

The preliminary review considered all the issues that the pharmapolitics manager had to be acquainted with to prepare for the lobbying process. Interviewees mentioned that these issues were:

- a) Identify the key people that need accessing. The first question that respondents asked themselves was- who is the person in this HMO or in government who achieves the action that I want? This item related to the sub-category **target for lobbying**, being the pharmacopolitics manager responsible for identifying the active **participant** to be lobbied.

“This is initiated with the investigation of who is responsible, either the Medical Practice Manager or the Auditor. Who is the key person for the incorporation of a **product**?” (Interviewee A, PH).

Previously known insiders in the HMO, managers of other companies, officials in other HMOs or other areas of government provided information about **the target for lobbying** to the pharmapolitics manager.

- b) Following the identification of the key person, the pharmapolitics manager assessed the information needed about this official. Pharmacopolitics managers focused on whether the official had a scientific profile, commercial profile or costs-oriented profile. They also looked for hobbies and personal information about the official.

“The first and essential factor is to be super-informed. What does that mean? You need to make an extensive analysis of the situation. Then a meeting must be arranged and that would be the first formal meeting where the purpose would be a very precise observation of the official...” (Interviewee C, PH).

- c) Another issue to be considered was investigating the habits of the HMOs, provinces or state. Was the HMO likely to receive rebates from the industry? Did it have a very restricted formulary? Was it an open formulary? It was also important to know the guidelines regarding the introduction of a **product** onto the formulary. Were there any compliance proceedings to take into account?

“If we speak about rebates for **products** prescribed for outpatients, the introduction of a **product** in an HMO with rebates implies that the **product** will have to contribute with those rebates”. (Interviewee E, PH).

d) Interviewees mentioned that if the official had been in position for sufficient time then the pharmapolitics manager should also investigate the receptive profile of the official. Was he/she eager to get information or was he/she more prone to receive contribution payments for the HMO or for himself/herself? Previous experiences of the pharmapolitics manager or from other members of the pharmapolitics establishment could help to have the right approach in the decisive moment.

“...one gets the impression in the first meeting about where the negotiation is heading for...” (Interviewee I, EX).

“...you also work with the training of the officials of that HMO...whether they are interested in going to a congress or to present a research study abroad. In these situations you have the opportunity to get closer...” (Interviewee A, PH).

Obtain access.

Respondents said that it was easy to obtain access to key people when there was a previous relationship. Pharmapolitics managers aimed to build long-term relationships with key decision making officials such as the big HMOs and some officials in the government. If there were changes, for example in the government, obtaining access was more difficult as the relationship had to be built again.

Most interviewees mentioned that access to people where there was no previous relationship was difficult. The first time there had to be an introducer, somebody connected with the official and who made the introduction. Respondents mentioned there were no access fees in these cases- the managers did not have to pay to meet an official or even the Minister of Health. Access was facilitated by people who knew the

officials and were somewhat connected with the pharmapolitics manager such as colleagues from other companies.

By this precept, respondents said that their range of acquaintances and facilitators had to be broad so that every time that there was a change or access was needed then they would have an opportunity to meet the key officials.

“...there are times that you help someone by introducing him to a certain official and there are times that you have no access to the official so you ask someone help you in that moment...” (Interviewee F, PH).

This possibility of access granting gave power to certain pharmapolitics managers over others. One respondent mentioned this issue and he called it: “a chain of favours” (Interviewee C, PH). A pharmapolitics manager granted someone access and he/she was then entitled to request support when he/she needed it. The one who had the most contacts could exert a power position in cooperative negotiations. It was also important when looking for allies. This was a self-profit equation:

“I can help you today but when I need an ally, I will be counting on you to support my position” (Interviewee C, PH).

Preparation.

Once the pharmapolitics manager obtained access and had information about the official that he/she was going to meet then the next step was preparation for the meeting. Respondents explained that the main issue was to prepare a dossier about the **product**. The pharmapolitics manager adapted this dossier to the specifications requested by the HMOs or the Ministry of Health. In some cases, like the PMO (National Formulary), the preparation of the dossier was a complicated task. This dossier focused mainly on

the scientific side of the **product**; it contained clinical trials showing efficacy and approval authorisations of the **product**. In cases where there were pharmaeconomics trials that showed the cost-effectiveness of the **product** these needed to be included. Local pharmaeconomics models were prepared taking into consideration the cost profile of the HMO. The pharmapolitics manager needed all potential evidence because did not know *a priori* which inquiries he/she would receive in the interview.

“You have to be really well prepared; to be a lobbyist implies that you go through continuous training. Suddenly, I have to learn about a new therapy for newborns and two days later I have to learn about a coronary disease and its treatment...” (Interviewee B, PH).

“...the introduction of a **product** in the PMO (National Formulary) requires that there is information that proves that the item is cost-effective compared to other options...there must be a benefit from the pharmacological perspective and from the economic perspective...” (Interviewee D, PH).

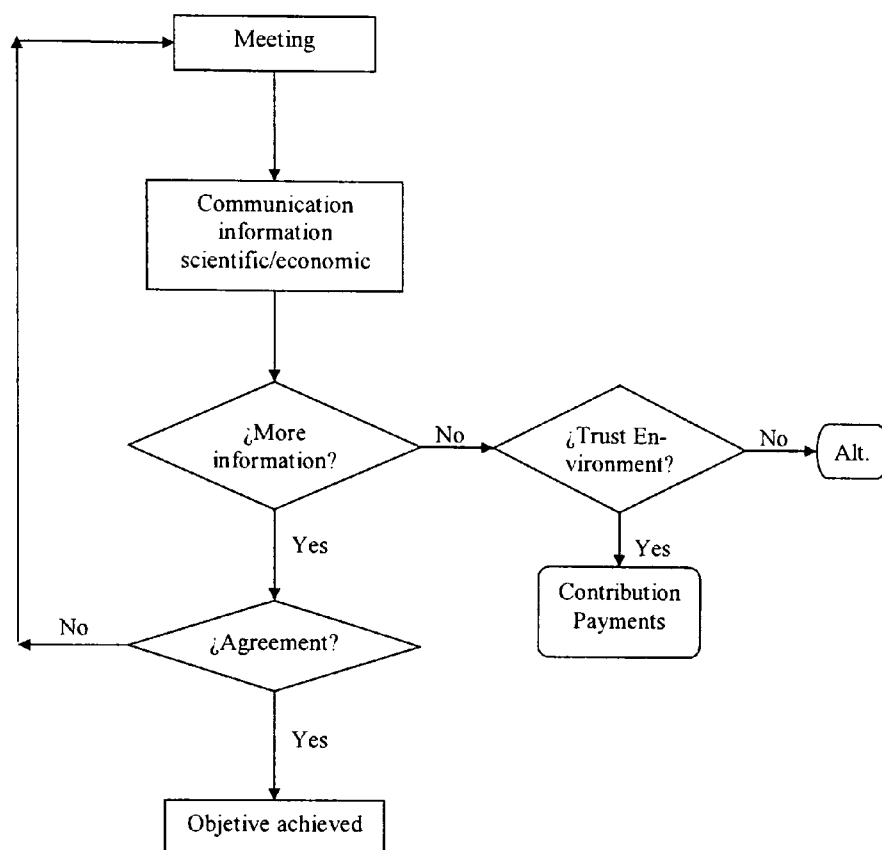
Once the dossier was complete, the pharmapolitics manager asked for an interview and the negotiation process began.

Negotiation.

The negotiation sub-process relates to the interaction with the official aimed at obtaining a desired action. In the lobbying definition of Moloney and Jordan (1996), planning would entail the *preliminary review*, *obtain access* and *preparation* sub-process and *negotiation* is the act of interest representation to decision makers. The negotiation sub-process began with the first meeting with the official. Respondents mentioned that, usually, the initial contact was in the office of the official. In cases

where there was a previous relationship with the official then the meeting could be in another place. Respondents clarified that meetings were never at the pharmaceutical company. Other places mentioned by the respondents were restaurants, bars or lobbies in hotels. Throughout the interviews it was clear that there was a standard negotiation procedure. The lobbying issue most mentioned by respondents was the introduction of **products** in a formulary therefore this issue was considered as an example for the description of the standard negotiation procedure. First of all the pharmapolitics manager asked the official for a meeting but without explaining the purpose of the meeting. The meeting was arranged and with the first contact between the pharmapolitics manager and the official the specific negotiation process began. The following diagram depicts the first stage of the negotiation process which entails sub-processes of the negotiation sub-process. Coding for process was used in the analysis of the negotiation sub-process. The sub-sub-processes identified permitted the development of the two stages of the negotiation process.

Figure 7 First stage negotiation process:



Firstly, the pharmapolitics manager made his/her purpose explicit and requested of the official the introduction of a **product** in the formulary. The pharmapolitics manager defended the introduction of the **product** with the transmission of the **product's** scientific information and the description of its therapeutic advantages. The **product's** dossier had been prepared for use in support of his/her statements and this was given to the official for study and evaluation. The pharmapolitics manager viewed the first interviews as simply being informative and did not expect the official to decide anything in the first encounter.

“First, a meeting is arranged. I believe that when the meetings come into question, there is always a hard position in the first one, the second one is more relaxed and in the third there is some agreement scenario...” (Interviewee A, PH).

Respondents said that observation in the first interview was essential to gauge the receptivity of the official to the issue. The pharmapolitics manager tried to emphasise the technical advantages for the patients of the HMO.

“The official gets scientific information, pharma-economics studies...in the case, that the official is not satisfied, I bring information about economics and costs for the HMO...” (Interviewee B, PH).

Respondents said that the first interview did not usually result in a decision and that the official usually declared that he/she will study the dossier. The official might request additional information. This information included, not always but frequently, pharmaeconomics studies.

“...one provides scientific information and you receive feedback from the committees or officials to whom you have presented the information. This feedback could be positive, there could also be an objection to some specific issue which needs more information, but normally the process advances” (Interviewee D, PH).

After the first interview, the pharmapolitics manager had to look for hints in order to decide whether the official was more interested in the scientific side of the **product** or was more prone to contribution payments personally or for the HMO. The profile of the official indicated which negotiation approach to follow.

“The first meeting used to be formal, an evaluation meeting, a study of the official...so that in this first meeting you get an idea of what should be the approach of the negotiation...” (Interviewee J, EX).

After considering the information from the interviewees the researcher developed a negotiation profiling matrix that showed which approaches should be followed based on the information already gathered in the preliminary review sub-process.

Table 16 *Negotiation profile matrix*

| <u>Official profile</u> | <u>Unknown</u> | <u>Referred</u> | <u>Established</u> <u>Relationship</u> |
|--|----------------|-----------------|---|
| Scientific Information | Exploratory | Exploratory | Confirmed |
| Contribution Payments (HMO or Private) | Exploratory | Exploratory | Confirmed |

If the pharmapolitics manager had an established relationship with the official and prior negotiations he/she would know whether the scientific information or contribution payments were more important for the official and could follow a safe strategy. If the pharmapolitics manager did not have a relationship with the official, but a colleague provided information about the profile of the official, the negotiation approach was exploratory; the pharmapolitics manager could not take for granted what the colleague had said. This information usually helped in the approach but, as the relationship was

personal and based on personal experiences with the official, it could not be assumed that the official would behave the same way with another pharmapolitics manager. The pharmapolitics manager had a hint of how to steer the negotiation but he/she needed to look for signs of approval. In the case of a new official without previous information, the approach would be exploratory. Respondents said that in this case the negotiation process was usually longer and the pharmapolitics manager had to go through the whole negotiation process as described in the first stage negotiation process model (figure 7).

After the first meeting new meetings were arranged; the pharmapolitics manager provided additional information and the discussion continued.. During this process the pharmapolitics manager made closer ties with the official and decided whether it was appropriate to continue with a transmission of information approach or to switch to a contribution payment approach. The decision to offer contribution payments or to continue offering information was taken in one meeting. The first step is the observation and analysis of the responses together with body signs. It was important to observe how the official reacts to the request of the pharmacopolitics manager. The pharmapolitics manager looks for hints that might indicate the course that the negotiation should take. Sometimes those hints are obvious and other times they are subtly insinuated.

Expressions like “it is too costly for the HMO...” (Interviewee O, HO) did not mean that the official was asking for a rebate or a contribution payment.

Therefore, the pharmapolitics manager had to introduce 'encouragements' in the conversation and evaluated the reaction to those proddings in order to determine whether the official was interested in scientific information or in contribution payments or in both. Once there was a clear reaction to a stimulus, the pharmapolitics manager could probe in that direction until the motivation of the official became clear. Then

he/she chose an approach and focused on it, contribution payments or communication of information or a mix of both.

The negotiation discussion might continue only based on scientific information. One example for this is the introduction of **products** in the National Formulary. The official should be persuaded by the pharmapolitics manager of the advantages of the **product** and he/she then decided that the **product** would be introduced. The negotiation process was finished and successfully.

However respondents mentioned that there were other cases where the pharmapolitics manager had to change approach and focused on contribution payments. There could be two modalities: the first one was that the official was aware of the incremental costs for the HMOs of the new **product** and tried to negotiate a higher rebate for the HMO. The second one was that the official wanted a contribution payment for his/her private interest. Interviewees remarked that even in the event of a contribution payments approach, the scientific phase was always present in the negotiations; it could be longer or shorter but it was always present in the negotiation.

“One tries to incorporate the **product** in the best way, but in this country there are aspects not related to the scientific evidence and not related to pharma-economics. At this stage it is the official who proposes some kind of agreement. You have to pay attention to where the conversation is leading”. (Interviewee A, PH).

“The second possibility is that there is a spurious interest...” (Interviewee B, PH).

If the pharmapolitics manager decided to explore a contribution payment approach, it was always necessary to have previously built a trust environment. No contribution payments negotiation could take place without trust between the official and the pharmacopolitics manager.

“...evidently in the relationship with the government and the HMOs it is essential that this relationship be properly established...good lobbying is also related to a deep relationship. You have a fluid contact, you build a friendship and some doors are opened so that you collaborate from another perspective”. (Interviewee D, PH).

In cases where there was no evidence of trust then the pharmapolitics manager would call for a break in the negotiations.

“...the first thing I would do is to see how to break down the barriers; I have to assume that they are there in a realistic way. If I cannot get beyond this barrier, is because my competitors are protected by some type of sinecure or some other doubtful arrangement that I have not implemented. I would stop the negotiations and try to get closer to the official” (Interviewee B, PH).

After establishing the trust environment the pharmapolitics manager could initiate the contribution payments approach. The manager should identify the type of contribution payment the official requires; either the type that benefited the organisation or the type that benefited the official directly. Those that benefited the organisation were reimbursements, or rebates, related to the use of the company's **products**.

“If we talk about rebates for **products** prescribed for outpatients, the introduction of a **product** in an HMO with rebates implies that the **product** will have to contribute with those rebates” (Interviewee G, PH).

Another type of contribution payment for the HMOs was the implementation of Disease Management Programmes⁴. These programmes were aimed at the treatment of a chronic pathology and the pharmaceutical company cooperated with part of the costs of implementation.

Con formato: Sin subrayado

Con formato: Sin subrayado

“It could happen that I have the need to introduce a certain **product** in the formulary, but the HMO has difficulties with a Disease Management Program that does not include my drug. If I cooperate with the implementation of the Disease Management Programme, even if it is not related to my **product**, I might be able to introduce my **product**...” (Interviewee A, PH).

When the contribution payments benefited the official directly then the official had deviated from the best interests of the HMO in pursuit of a private interest. Respondents mentioned that officials tried to disguise the private contribution payment as also achieving a benefit for the HMO.

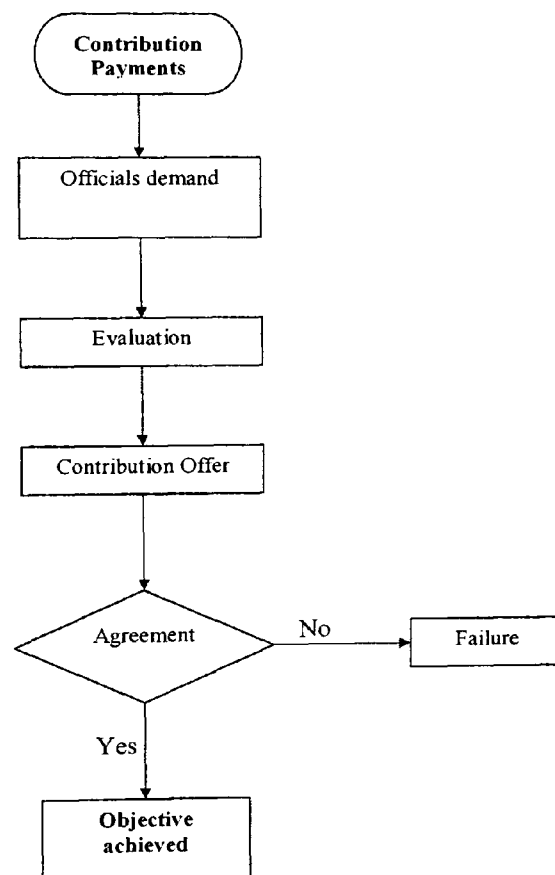
“The second possibility is that there is a spurious interest. Usually in Argentina, the spurious is not totally spurious; it looks towards the convenience of both parties, HMO and official. So that the spurious is not noticed there is a benefit for the HMO and a benefit for the patient of the HMO” (Interviewee B, PH).

“Usually, this type of arrangement has two perspectives: it benefits the HMO and it also leaves an extra benefit for other parties” (Interviewee I, EX).

⁴ A program that bundles use of prescription drugs with physicians and allied professionals, linked to large databases created by HMOs, to treat people with chronic diseases. The claim is that this type of service provides a higher quality of care at more reasonable price than an alternative, presumably more fragmented, care.

Once the pharmapolitics manager had implemented the contribution payments approach the process was always the same irrespective of the type of contribution payment. The second stage of the negotiation process included the contribution payments sub-process and the following figure shows the contribution payments process. As mentioned before, coding for process was used to identify the sub-processes in the negotiation sub-process. The researcher divided the negotiation sub-process in two stages to facilitate the description of the substantive theory.

Figure 8 **Second stage Negotiation process**



First, the pharmapolitics manager made clear to the official the understanding that there was the possibility of contribution payments. The official requested a certain contribution payment.

“...that you have to give some contribution for what is permitted. That it is not the same as contributing for something illegal” (Interviewee B, PH).

The pharmapolitics manager evaluated the request and considered whether the cost-benefit was acceptable. The pharmapolitics manager could make a lower offer than that demanded by the official. There would be an interaction of contribution offers and negotiation until there was consensus on both sides. Both parties would arrive at a position where both had won or at least had an acceptable result.

Results

Results were positive in cases where the lobbying was effective and the desired action implemented. It was irrelevant for the analysis of success whether there was only communication of information or contribution payments were needed.

What happened in the cases where there was no agreement? The process failed and the pharmapolitics manager was pressured by the company to achieve its objectives:

“... the sales manager pressured me to have this **product** introduced in the formulary...” (Interviewee E, PH).

The pharmapolitics managers said that at this stage they looked for alternatives. The alternatives mentioned were:

1. The pharmapolitics manager approached a higher-ranking official in the organisation, HMO or government and restarted the whole process.
2. The pharmapolitics manager hired a free-lance lobbyist with an established relationship with the official and restarted the process. This alternative had an additional cost for the company. It was also mentioned that in this

alternative, the company lost control of the situation as somebody else was negotiating on its behalf.

The pharmapolitics managers mentioned that there were a few cases when the objective could not be achieved but generally the rate of success was higher than the failure rate.

Question eleven, twelve (Sub-Category = cooperative lobbying)

Is pharmaceutical lobbying carried out alone or in a cooperative way?

Do you think that it is possible to free-ride?

This research focused at first on individual lobbying but further reading of the literature prompted the researcher to investigate cooperative lobbying. Cooperative lobbying was regarded in this research as lobbying exerted by a chamber or a group of companies with a common objective.

Respondents mentioned that cooperative lobbying was frequently used especially in regards to legislation, ministries of health (national or provincial), large HMOs or large PBMs. The objective was to concentrate forces in order to be a more powerful negotiating force. Cooperative lobbying was used when the **target for lobbying** was more powerful than the individual companies.

“...the argentine negotiation...on one side it is cooperative...” (Interviewee S, SD).

“...and this cooperative activity also requires that the pharmaceutical companies and their pharmapolitics managers participate in the cooperative part...” (Interviewee J, EX).

The objective of the cooperative lobbying was to negotiate from a stronger position than by lobbying alone. It should be noted that all respondents mentioned that cooperative lobbying was always used when the other party was the government; in case of large

HMOs it was also used. The modalities of cooperative lobbying could be lobbying exerted by the multinational companies chamber or a group of companies lobbying as a cartel. Respondents also mentioned that in the case of cooperative lobbying, national and multinational companies joined forces to achieve the objectives pursued.

“...multinational companies and national companies applied pressure to change the Reference Prices decree to a reasonable situation...” (Interviewee B, PH).

“...I believe that the key issue here is specifically the cooperative lobbying business” (Interviewee L, EX).

“...CAEMe, the chamber, is always in negotiation with PAMI (pensioners HMO) for an increase in the capita...” (Interviewee F, PH).

The multinational companies also joined forces with the American Embassy. The officials at the chamber had close contacts with the officials of PhRMA (Pharmaceutical Manufacturers of America). The petitions to the American Embassy were channelled through PhRMA and the big American companies.

“...the American Embassy....was more proactive regarding pharmaceutical **products**... specifically in the issue of the Patents Law” (Interviewee D, PH).

Cooperative lobbying improved the position of the pharmaceutical company against large organisations. Even then the pharmapolitics managers mentioned that they had to use both types of lobbying to be effective: individual and cooperative.

“...the one responsible for pharmapolitics should take into account both scenarios: first, the cooperative action and then the individual action. It does not mean that the cooperative is more than the individual, both things at the same time”. (Interviewee J, EX).

Individual lobbying needed to be pursued with big HMOs or with the government because **cooperative lobbying** might not be beneficial to the interests of one company. **Cooperative lobbying** did not look after the particular interests of one company but to the interests of the industry. The pharmapolitics manager would lobby the officials in big organisations to achieve minor changes in what had previously been agreed collectively. These minor changes could mean a huge difference for the individual company.

“...how to achieve, in a framework, what has been previously collectively negotiated, a benefit for one’s **product** or have an advantage over my competitors...” (Interviewee A, PH).

Cooperative lobbying was executed by the chambers or group of companies and was frequently used when the **targets for lobbying** were the big HMOs or the government. The reason why cooperative lobbying occurred was the size and importance of the **target**. One example mentioned (Interviewee C, PH) was the boycott against the implementation of the generics law introduced by the Ministry of Health. The law stated that physicians should only write the name of the drug in a prescription and not the trademark. Therefore the patient in the pharmacy could choose the most convenient alternative. This regulation left the decision in the hands of the pharmacist and the patient. The pharmaceutical industry implemented a boycott through the HMOs formularies and conditioned payment of rebates to HMOs to the acceptance of prescriptions with trademark. The HMOs decided to continue receiving the rebates and did not enforce the rule to physicians about prescribing only with the name of the drug, thus accepting the use of trademarks in the prescriptions.

The twelfth question was whether it was possible to free-ride. This concept was present in all the literature about lobbying. In the first three interviews with pharmapolitics

managers this concept was absent. The researcher subsequently introduced this question to prompt responses. Even then the pharmapolitics managers were not very explicit about the subject. They simply mentioned that it was difficult to free-ride because of the coercion of other companies. The external lobbyists' interviews provided the data needed to analyse this concept in the Argentine context. One of the external lobbyists said that free-riding was not common because those companies that attempted to free-ride were then punished by the others by exclusion from the HMOs formularies. The *industry*, in these situations, would act in a cooperative way. Free-riding was almost non-existent because the big companies had the power to enforce punishments and the penalties for free-riding were high. Olson (1965) confirmed this attitude when he stated that rational individuals would decline to contribute to the costs of collective action unless there was coercion. Respondents' quotations confirm this issue:

"...in the case that one company does not follow the cooperative action, this company is punished..." (Interviewee T, SD).

"...punishment could be having the company excluded from all formularies meaning that they would lose a substantial share of the market" (Interviewee J, EX).

Sales directors and marketing directors from companies that did not have a pharmapolitics manager also confirmed this concept. These companies relied on the Chamber for the introduction of the **products** in the formularies.

"...I know the Chamber is not working for us, but we benefit from their actions in PAML..." (Interviewee S, SD).

They agreed that the punishment for free-riding was to be excluded of all formularies and from the industry negotiations. This comment proved that free-riding was only

possible when the advantages of free-riding were high and the other members of the group did not have the power to punish the free-rider for its behaviour.

“...we just follow what the Chamber or the big companies tell us to do ...” (Interviewee S, SD).

“...specially avoiding conflicts with the establishment...” (Interviewee V, SD).

The respondents from companies without a pharmapolitics manager said that they complied with the rules imposed by the establishment. Although free-riding could be a natural behaviour of companies in the Argentine context, companies avoided this because of the penalties involved.

The researcher has explained the findings of the research based in the interview questions. The researcher had made no question about the ethical considerations of respondents as the aim of this study was to abstract from the ethical issues. Nevertheless, the researcher found in the open coding process that the ‘ethics’ emerged as a concept. The researcher decided to comment briefly this concept although it is not the aim of this research.

The researcher noticed that ethical considerations were made all through the research even if respondents never mentioned the word corruption. The fact that contribution payments are made directly to officials, with the aim of deviating the officials from the best policy, is accepted by all respondents. Most respondents experienced corruption in dealings with the government. The government corruption generated funds to be used to finance the ruling political party. Confronted with the issue that there was corruption in the health care sector, pharmapolitics managers showed an ambivalent feeling about corruption. They felt that it was not right to enter into corrupt practices but, as they saw

it, there was no choice. All pharmapolitics managers thought that the goal justified the means. It seemed like a necessary part of the job description.

Corruption and its rationale have been discussed by numerous authors but it was not an objective of this study, which only focused on the implementation of lobbying, not on its moral consequences. The researcher has no plans to develop in the future any research related to corruption in the pharmaceutical lobbying and its implications.

5.4 From the data to the categories

The two research questions were answered in the emergent theory: why and how the pharmapolitics managers perform their lobbying? The fixed set of questions and the participant observation permitted the collection of almost all the data used in this research. *Open coding* was used for questions 1, 2, 3, 4, 5, 11 and 12. *Coding for process* was used for the questions 5 (building trust), 6, 7, 8, 9 and 10 (lobbying process). The *conditional matrix* was used as an analytical device helping to identify the relationships between the different sub-concepts, conditions and consequences. Through the process of *axial coding*, the researcher identified the relationship between the concepts, sub-concepts, properties and processes. Sub-categories emerged as aggregates of the most closely interrelated elements for which supporting evidence was strong. The researcher identified seven sub-categories. These categories were defined as a fundamental class or division of data. In the context of this research they represent a fundamental issue or topic concerning pharmaceutical lobbying. A full tabulation of the seven sub-categories, together with the concepts, processes and properties, is included

as an Appendix 2⁵ to this research. The seven sub-categories derived in the study are as follows:

Table 17 *Sub-Categories*

| <u>Sub-Categories</u> |
|-----------------------|
| Target for lobbying |
| Motivations |
| Participants |
| Product |
| Building trust |
| Strategy |
| Cooperative Lobbying |

Each of these sub-categories is a cluster concept that captures an important explanatory aspect of the overall phenomenon of interest; why and how multinational pharmaceutical companies perform lobby operations in Argentina. The naming of the categories was arbitrary. In each case, it represented an attempt by the researcher to capture and imply the logic that tied together the various concepts and properties. That the research was carried out in Spanish proved to be another obstacle for the adequate naming of the categories. The researcher had done all the coding process (open, axial and process) in Spanish so that when he identified the seven sub-categories, he had the

⁵ The labels included in the Appendix shows only a selection of those identified in the process of open coding.

appropriate name in Spanish. Literal translation is not adequate in this case. An example of this would be the sub-category “Cooperative lobbying”. In Spanish this sub-category would be named “Corporative lobbying” and this has the same meaning as “Cooperative lobbying” in English. Being able to express my thoughts clearly has always been a major concern to me when I spoke my native language Spanish; so that trying to translate the appropriate name for the sub-categories has been a difficult task. The sub-categories showed the researcher the logical way to the identification of the core category.

5.5 Core category

Finding the core category- the one that integrates all the other major categories- is the aim of *grounded theory*. By using selective coding the researcher went through the process by which all categories were unified around a core category (Strauss and Corbin, 1990). Selective coding required the selection of the focal core code that was the central phenomenon that emerged from the selective coding process. This focal core code for this research was **pharmaceutical lobbying**. Seven sub-categories were found in the axial coding process. These sub-categories were related to the core category, **pharmaceutical lobbying**. These categories were classified as representing context, conditions, actions, interactions and outcomes. The basic questions “why, who, what and how” are represented in the sub-categories. The researcher developed a theoretical framework of interrelated concepts that showed posited relationships between the pharmaceutical lobbying identified in answer to the fixed set of interview questions. The questions and participant observation aimed to identify what was the central activity occurring here, what were the conditioning or influencing concepts, what were the observable outcomes and any intervening concepts and variables being represented by the sub-categories (Strauss and Corbin, 1990). The selective coding stage integrated

the seven sub-categories in what emerged as the core category, **pharmaceutical lobbying**. **Pharmaceutical lobbying** as a core category has analytical power. “What gives it that power is its ability to pull the other categories together to form an explanatory whole” (Strauss and Corbin, 1998, p.146). Following the grounded theory methodology the seven sub-categories, found in the axial coding process, provided the basis to explain the substantive theory in the research.

5.6 Substantive Theory

The researcher addressed the two research questions of ‘*why*’ and ‘*how*’ the pharmaceutical industry carried out its lobbying. The **target for lobbying**, for the pharmacopolitics manager, was the official. There had been a transfer of decision-making power from the physician to the official so that the official now decided what the physician should prescribe. The officials exerted their power through the formularies by introducing or removing drugs. The pharmacopolitics manager **targeted** the official **for lobbying** in order to have the company’s **products** introduced onto formularies. Regarding the question ‘*why*’ was pharmaceutical lobbying carried out, the researcher identified five **motivations**. Respondents stated three **motivations** explicitly: introduce products onto the formularies, maintain market share in the formularies and increase sales and profits. The researcher identified two implicit **motivations**: to influence decisions and simplify future negotiations. The basic research question ‘*who*’ developed into ‘*who* were the **participants** in the **pharmaceutical lobbying** process’ during the emergence of the fixed set of questions. The researcher recognised nine **participants**: pharmacopolitics managers, public officials, HMO officials, pharmaceutical companies, government, HMOs, the multinational companies Chamber (CAEMe), the American Embassy and the free-lance lobbyists. The researcher classified them according to their degree of participation in the **pharmaceutical lobbying** process- pharmacopolitics

managers, public and HMO officials were identified as active **participants**; pharmaceutical companies, the government and HMOs as passive **participants**; and the multinational companies Chamber (CAEMe), the American Embassy and the free-lance lobbyists as occasional **participants**. Pharmacopolitics managers agreed that **building trust** and the **product** were the keys to success in **pharmaceutical lobbying**. **Product** related to having a **product** with certain intrinsic properties such as quality, scientific support, being essential for the health of the patients and being broadly used. On the other side there were some perceived properties (scientific value, economic value and social value) that officials and pharmacopolitics managers regarded as important for the policy decision. The basic question of '*what*' was the physical item in the lobbying process, was addressed: it was the pharmaceutical **product**. Pharmacopolitics managers lobbied for the pharmaceutical product to be included in a formulary. **Building trust** related to building a relationship with the official and to creating a negotiation environment for the **pharmaceutical lobbying** process. **Building trust** was a process and coding for process was used for its analysis. The pharmacopolitics manager had to build a relationship (close, informal, long-term) with the official so that **pharmaceutical lobbying** could take place. This relationship was essential for any lobbying activity. Once the relationship was established, the pharmacopolitics manager had to create a negotiation environment for the **pharmaceutical lobbying** process. The pharmacopolitics manager had to delineate his/her **strategy** to lobby the official. The researcher identified four sub-processes and one output in the **strategy** sub-category. The sub-processes were *preliminary review*, *obtain access*, *preparation* and *negotiation*; the output was *success or failure*. *Preliminary review* referred to the collection of information about the official and the HMO by the pharmacopolitics manager to prepare his/her **strategy** for the lobbying process. After that, the pharmacopolitics manager tried to *obtain access* to the official. If there was an existing relationship, this posed no

problem. In cases where there was no existing relationship, a third party (colleagues, free-lance lobbyists) was used to gain access. After *access* was *obtained*, the pharmacopolitics manager prepared the dossier of the product (scientific evidence) aimed at transmitting information about the product or technology to the official. The pharmacopolitics manager arranged the meeting with the official and the *negotiation* process began. At the meeting, the pharmacopolitics manager requested a desired action, i.e. the introduction of a product in a formulary, and gave the dossier to the official. The official asked for more information or acceded to what the manager requested. The pharmacopolitics manager had to adapt his/her lobbying **strategy** according to the previous information gathered and the signals received from the official. The *negotiation* continued with the transmission of information until achievement of the expected result. In the case where the negotiation did not advance, the pharmacopolitics manager could decide to follow a contribution payments **strategy**. A trust environment between the official and the pharmacopolitics manager had to exist for there to be a contribution payments **strategy**. The official requested a contribution payment for himself/herself, either for the HMO or for both. The pharmacopolitics manager evaluated the request and *negotiated* with the official until reaching an agreement. In cases where that did not happen, the pharmacopolitics manager would look for an alternative **strategy** to achieve his/her objective. The pharmacopolitics manager would try to gain access to a higher-ranking official in the organisation or would hire a free-lance lobbyist to carry out the lobbying of the official.

Pharmaceutical lobbying could be carried out singly or in a **cooperative** way. **Cooperative lobbying** was considered in this research to be lobbying exerted by the Chamber (CAEMe) or a group of companies with a common objective. The researcher identified that **cooperative lobbying** was used when the **targets for lobbying** were

large organisations such as HMOs or the government. The reason being that a coalition of companies can negotiate from a stronger position than from lobbying alone. In **cooperative lobbying**, the group exerted pressure and the HMO or the government was unable to outmanoeuvre the group members. Individual companies also lobbied large HMOs and the government for minor changes as **cooperative lobbying** did not look after the particular interests of one company but only to the interests of the coalition. Free-riding was not possible in the context of **pharmaceutical lobbying** in Argentina because of the coercion exerted by the largest companies- the punishment being the exclusion from the formularies and from the industry's negotiations. **Pharmaceutical lobbying** as a core category addressed the two research questions of 'why' and 'how' the pharmaceutical industry carried out lobbying. The substantive theory also found that corporatism was the predominant theory in **pharmaceutical lobbying**. No evidence was found that supported the pluralist theory.

5.7 Conclusion

This chapter developed the substantive theory found in the process of the research. *Grounded theory* was used as a methodology and the substantive theory was grounded in the data. The emergent theory is supported by all the data gathered. Seven sub-categories were identified and through the selective coding one core category was identified, **pharmaceutical lobbying**. The findings of this research supported earlier studies on the lobbying theory. It also provided new insights in the process of *pharmaceutical lobbying*. Locke (2001) identified two common approaches; a) the literature is interwoven with the data, b) the findings from the data are presented separately and the integration of existing theory and research delayed until the discussion section. The researcher took the latter approach. The findings were reported

separately from the integration of substantive with formal theory and were dealt with in the following chapter.

CHAPTER 6: CONCLUSIONS

6.1 Introduction

This chapter deals with the substantive theory discussed in chapter five and compares it with the formal theory of lobbying. This process aims to strengthen the external validity of the substantive theory. External validity requires establishing clearly the domain to which the study's findings can be generalised. Here, reference is made to analytical and not statistical generalisation and required generalising a particular set of findings to the broader theory of lobbying and not broader population. Three main topics discussed in this chapter:

- a) The linkage of the emergent theory with the macro-theory of lobbying.
- b) The linkage of the emergent theory with the meso-theory of lobbying.
- c) The linkage of the emergent theory with the micro-theory of lobbying.

Through these linkages the researcher aimed to verify or dispute the formal theories based on the research data. The discussion of the substantive theory with the formal theory enabled the researcher to develop the conceptual findings. This research was supported by theories of lobbying; the macro-theory, the meso-theory and the micro-theory. Elements of each emerged from the data in all parts of the research. The comparison of the formal theory with the substantive theory improved external validity by establishing the domain to which the study's findings can be analytically generalised. The limitation of the conceptual findings was that they were related only to the pharmaceutical lobbying performed by multinational pharmaceutical companies in Argentina. Further research is required to establish whether the conceptual models

developed in this research could be applied to another country or context.

Four models have been developed to illustrate the conceptual findings. These models derived from the discussion of the formal theory and the substantive theory. Two of them were related to the macro-theory of lobbying and the other two to the meso-theory of lobbying. A conceptual model based on the micro-theory of lobbying was not developed because this theory was the application of lobbying in specific situations and this issue has been extensively explored in the Substantive Theory chapter. Nevertheless, the differences to the situation in the USA have been pointed out.

The four models are:

- a) The position of the pharmaceutical industry in the corporatism-pluralism scenario.
- b) Comparison of lobbying styles.
- c) The pharmaceutical lobbying process.
- d) The cooperative and individual lobbying strategy.

The researcher has discussed the limitations of the study, suggested recommendations for further research and dealt with the implications of the study for professional practice.

6.2 Discussion of the substantive theory with the formal theory

6.2.1 Substantive theory and formal macro-theory of lobbying

Pluralism, where power was spread throughout society with no particular sector being dominant, was antagonist to the role of pharmaceutical industry as an interest group in

their relationship with government and HMOs. Felicio (2002) remarked that there were no other power sources or interest groups who balance the relationship of the pharmaceutical industry with the government and HMOs. The pluralist model of competing interest groups that tried to influence government decision was not found in the substantive theory. The substantive theory showed only one interest group, the pharmaceutical industry as a corporation or coalition, which built close ties with the government and HMOs to pursue its interests. There was no bargaining between interest groups as Dahl & Lindblom (1976) suggested so pluralist theory was not applicable to the pharmaceutical industry as an interest group.

Nevertheless some elements of pluralism were found in the substantive theory. One was the polyarchy concept developed by Dahl (1991) who stated that interest groups had unequal resources to influence government or officials. The pharmaceutical industry was one of these groups, with plenty of resources to influence government. It hired its pharmacopolitics managers to exert more influence on government decisions than other interest groups. Truman (1951) did not believe in the equality of groups as he felt that any system tended to discriminate in favour of established groups and interests; this could be seen in the close ties between high ranking officials and pharmacopolitics managers. The assertion by Lindblom (1977) and Grant (2002) that business occupied a privileged relationship with decision-makers was supported by the substantive theory. Lindblom & Braybrooke (1963) introduced the theory of incrementalism where the players learnt from experience and increased their power in a certain sector or area. This was essentially true in pharmaceutical lobbying because greater lobbying by pharmacopolitics managers of the officials resulted in a better established relationship and this further facilitated the process of lobbying.

The pluralist model of different interest groups competing with each other in different areas of influence and with different powers was not supported by the substantive theory. Substantive theory showed no competition with lobbying groups or lobbying actors.

The position of the pharmaceutical industry was definitively more closely related to corporatism. The pharmaceutical industry in Argentina was a major interest group with close ties to the government and power to influence its decisions. Shonfield (1965) observed that the major interest groups, such as the pharmaceutical industry, were brought together and encouraged to conclude a series of bargains about their future behaviour which would have the effect of moving economic events along a desired path. Schmitter (1974) stated that in a corporatist system there were few groups, each in a specially privileged relationship with government. This statement described the relationship that the pharmaceutical industry maintained with the government and HMOs. Schmitter (1974) also remarked that in corporatism the constituent units were recognised by the state and granted a deliberate representational monopoly within their respective categories. That held for the pharmaceutical industry in Argentina as no other interest group was in competition with the industry's interests (Felicio, 2002). Lehmbruch (1977) placed greater emphasis on policy making in which concerted action assumed central importance. Lehmbruch saw corporatism as an institutional pattern of policy formation in which large interest organisations, like the pharmaceutical industry, cooperated with each other and with public authorities in not only the articulation and even intermediation of interests but also in the authoritative allocation of values and the implementation of policies. A case that illustrated this collaboration was the pharmaceutical industry's cooperation with the Health Superintendence in the modification of the reference-price decree. Crouch (1983) stated that insider groups

were incorporated in decisions and played a structured and significant role in policymaking; the pharmaceutical industry could be identified in the substantive theory as an insider group in the process of decision making. The existence of outsider groups following Grant's (1989) classification was not supported by the substantive theory.

Schmitter (1974) defined corporatism as a structure of interest representation and Lehmbruch's (1977) corporatism as a system of policy making. The pharmaceutical industry, as a corporate member, represented the interests of its members acting on its behalf. On the other side, the pharmaceutical industry is consulted by the government in policy issues, having a dominant role in the policy outputs. Cawson's (1985) view amalgamated both perspectives. Adapting his definition to the reality of the pharmaceutical industry, it can be said that corporatism was a specific socio-political process in which the pharmaceutical industry, representing its monopolistic functional interests, engaged in political exchange with state or private health care agencies over public policy outputs in a role that combined interest representation and policy implementation through delegated self-enforcement.

The concept developed by Wassenberg (1982) was an advance towards a better definition of the role of the pharmaceutical industry in the corporatist model. This concept (Wassenberg, 1982) examined the role of collective actors, not government but companies, which hovered around and defended the specific interests of sectors like the pharmaceutical industry. Wassenberg (1982) argued that corporatism could exist at three levels, according to the specialisation of the actors involved:

- a) Macrocorporatism represented the peak institutions of the politico-economic body like congress.

- b) Mesocorporatism related to the institutionalised entity of complete industries which is represented in this research by the pharmaceutical industry and its chambers.
- c) Microcorporatism, which in this research was the individual pharmaceutical company or the pharmapolitics manager and thus is the lowest unit of political body.

The mesocorporatism perspective had a less ambitious understanding of corporatism as a sectional limited form with an empirical approach. The introduction of the meso- and micro-concept was vital in defining the role of the pharmaceutical industry, the chambers and its pharmapolitics managers in order to integrate them into the corporatist concept. This related to the interviews and the substantive theory in terms of the action of individual companies when lobbying HMOs and officials at a micro-corporatism level. When the industry performed cooperative lobbying, either through the chambers or through a coalition of companies, they fitted in the meso-corporatism concept.

The view of corporate pluralism formulated by Kvavik and Heissler (1974) was not supported by the substantive theory. Kvavik and Heissler (1974) described corporate pluralism as a process of co-optation whereby groups were offered representation in policy-making circles in exchange for supporting the resulting policies, even if the policy was not exactly (or even very close to) what the group desired. The pharmaceutical industry did not support policies that were not close to those that it desired. An example was the boycott against the implementation of the generics law introduced by the Ministry of Health. The law stated that physicians should only write the name of the drug in a prescription and not the trademark. Therefore the patient in the pharmacy could choose the most convenient alternative. This regulation left the decision

in the hands of the pharmacist and the patient. The pharmaceutical industry implemented a boycott through the HMOs formularies and conditioned payment of rebates to HMOs to the acceptance of prescriptions with trademark. The HMOs decided to continue receiving the rebates and did not enforce the rule to physicians about accepting the use of trademarks in the prescriptions.

Kelso's (1978) view largely reflected the role of the pharmaceutical industry as an interest/pressure group. He stressed the importance of cooperation between interest groups and government agencies, and of building networks between private groups and the government to make decisions on policy. These networks were described in the substantive theory chapter in the category "building trust". Kelso's (1978) model comprised a political system broken into a series of autonomous fiefdoms presided over by interest groups, like the pharmaceutical industry, that cooperated with the government and had an important role in decision making.

Regarding the interest group theory, the pharmaceutical industry fitted in Salisbury's (1984) definition when he mentioned that the classic view of the interest group omitted individual corporations like the pharmaceutical industry. Olson (1965) raised an important issue that was supported by the substantive theory namely that an interest group would decline to contribute to the costs of collective action, and thus would free ride, unless there was coercion to force it to do otherwise (Maloney & Jordan, 1997). These organisations should have "the authority and capacity to be coercive or have a source of positive inducements that they can offer the individuals in a latent group" (Olson, 1965, p.34). In the substantive theory it was demonstrated that the pharmaceutical industry coerced its members and that punishments were applied to free-riders such as exclusion from the formularies. This coercion was applied by the Chambers or by groups of large companies. In this way members joined for selective

incentives (Olson, 1965) such as inclusion of the products in the formularies; moreover, coercion was a means of inhibiting free-riding.

For Olson (1965) lobbying was a by-product of large economic groups that obtained their strength and support because they performed some function for the group interests. The substantive theory did not support this assertion. Lobbying was the principal way to achieve the legislation that would benefit the whole group. The substantive theory supported the existence of organisational entrepreneurs (Salisbury, 1969) in which chambers executives or coalitions leaders guided the other companies. The group maintenance issue was regarded as an exchange situation in which entrepreneurs lobbied for the rest of companies in specific issues, which they offered to members at a price, namely membership (Jordan & Richardson, 1987). Walker (1983) introduced the concept of *patronage* as means of maintaining the groups; a concept that was not supported by the substantive theory, but the researcher observed that there was *patronage* of the Multinational companies chamber (CAEMe) as it was funded by its member companies.

Salisbury (1984) argued that interest representation was dominated by institutions such as corporations and local government. He maintained that the classic view of the interest group omitted individual corporations, state and local governments, universities, think tanks and most other institutions of the private sector (Jordan and Richardson, 1987). As mentioned before, the pharmaceutical industry had to be considered as within this type of interest group. Moloney and Jordan (1996) also noted the interaction of corporations with government decision making circles. Howell (2004) referred to this issue saying that they were the type of organisation whose political task was to reflect the interests of the economic or occupational section that they represented. The substantive theory showed how the chambers lobbied for the interests of the pharmaceutical industry. The

pharmaceutical industry complied with Richardson's (1993) definition as a pressure group that articulated demands that the authorities in the political system should make an authoritative allocation; in its activities, the pharmaceutical industry did not seek to occupy the position of authority. Woll (2006, p.465) noticed that the term "interest groups" excludes firms and their political influence and her approach was: "Lobbying is all the activities by private actors aimed at influencing political decision-makers", including firms as "actors" but not as "interest groups". This assertion was firmly supported by the substantive theory as firms were active participants in the pharmaceutical lobbying process. Within the companies, the pharmacopolitics managers were the individuals who acted as 'lobbying actors' representing the interests of companies. Coen (1997) showed that individual firms were important political actors and studies had increasingly focused on new groups and *ad hoc* alliances rather than on traditional interest groups. Coen's view was also found in the substantive theory; the companies build coalitions to lobby the government or large HMOs.

Lobbying has to be understood by looking at the context in which interest groups were trying to act. Pharmaceutical lobbying in Argentina was different from the US and EU. The researcher developed a lobbying style framework of pharmaceutical lobbying based on the one presented by Woll (2006). The organisation of interest representation in Argentina had three modalities: one was the national Chamber of Multinational Companies (CAEMe) which lobbied the government and the large HMOs, the other was issue-specific coalitions between a group of companies that also lobbied the large HMOs and the last was the direct lobbying of the individual company (oriented at HMOs and officials) through its pharmacopolitics managers in issues related specifically to products. The instruments available in the three modalities were transmission of information and contribution payments. Pharmacopolitics managers

acted in the formulation of policies or in the formulation of formularies. There were revisions whereby pharmacopolitics managers tried to change what had been agreed by the Chambers or the coalitions in cooperative lobbying. The relationships between the pharmacopolitics managers and the officials tended to be long-term, not issue oriented and based on reciprocity. Pharmacopolitics managers expressed their demands in a direct way. Most of the time when there was a relationship the demand was direct and based on the information provided by the pharmaceutical companies.

6.2.2 Substantive theory and formal meso- theory of lobbying

This section analysed the findings of the research compared to the meso-theory of lobbying which determined two channels of influence: contribution payments and transmission of information. Both channels were used in pharmaceutical lobbying in Argentina. For the discussion of the formal theory, transmission of information was dealt with first. Fundamentally it is as described in the substantive theory; this instrument was used first by pharmacopolitics managers in their lobbying of officials.

The different models created by different authors were discussed to assess the meso-theory of lobbying with the substantive theory. The reduced form lobbying models were basic and they did not consider certain aspects of individual behaviour in the process of lobbying but despite this they were the starting point for the various models.

Substantive theory suggested that pharmaceutical lobbying fits in the “regulatory approach”, as first proposed by Stigler (1971) and formalised by Peltzman (1976). The lobbying process was implicit, assumed that the official set a policy in order to maximise a weighted sum of special interests’ utility and aggregate welfare. The regulatory approach focused on the determination of the policy outcome, such as the introduction of a product in a formulary, and that pharmacopolitics activities led to a

policy bias in favour of a certain company or group of companies.

The "policy formation approach" developed by Becker (1983) was not supported by the substantive theory of pharmaceutical lobbying in Argentina. In this model, two opposing lobbies used contribution payments to influence the official towards a decision favourable to their special interests. In the case of this research the model was not applied because either the pharmaceutical industry acted in a cooperative way- lobbying as an interest group the government and big HMOs- or on a micro-level when a company pursued the introduction of a new product in a formulary. On the micro-level there was no competition trying to counteract the company's activities. The only event in which there were two opposing lobbies was the issuing of the patent law in congress. At that time multinational companies lobbied through the American Embassy against the national companies who tried to counteract this lobbying.

Officials had an incentive to listen when they were imperfectly informed because the pharmaceutical industry had better information about the relevant issue than the officials, independent of whether it was a product or a new technology. This related strongly to the concept of "bounded rationality" developed by Simon (1955). Officials faced uncertainty about future policies and they could not incur in costs in acquiring information. These two factors, thus, limited the extent to which officials could make a fully rational decision. Simon (1955) claimed, they had only "bounded rationality" and officials were forced to make decisions not by "maximisation" but by "satisficing", based on the information provided by the pharmacopolitics managers. The huge amounts spent on the research of a new product ensured that pharmaceutical companies had the most complete information available about the new product or technology. The officials did not have the same information thus were imperfectly informed about the subject to be evaluated. This situation generated an information motive for lobbying.

Extensive information about a new product gave pharmaceutical companies the chance to influence the officials' decision through the provision of whole or part of this information. Different "transmission of information models" were developed by different authors and they were assessed against the substantive theory of this research. These abstract models were adapted to the pharmaceutical lobbying context. Words such as agent and principals were changed for official and companies.

The models of Potters and van Winden (1992), and Ainsworth (1993) were basic communication models. These models were supported by the substantive theory. The official had little knowledge about a new product or technology. The task of the official was to choose a correct policy under uncertainty and bounded rationality (Simon, 1955). The company, through the pharmacopolitics manager, provided the official with a dossier of necessary information so that he/she could evaluate the new product or technology. The official had to decide whether to trust this information received from the company or could ask for additional information to be "satisfied" with his/her decision; again, the company could provide this information to the official. The pharmacopolitics manager aimed to influence the official's decision with the provision of information. The two models mentioned above divided the companies into good and bad type lobbies. The substantive theory could not evaluate through the data whether the officials regarded companies as good or bad. It was already mentioned in the substantive theory that the officials regarded the pharmaceutical industry as a necessary evil so it was clear that there was a negative attitude from officials towards pharmaceutical companies in general. It was also the case that officials regarded the scientific information provided by pharmacopolitics managers as reliable.

Austen-Smith and Wright (1992) focused on the counteractive lobbying of two interest groups with opposing interests. This model was not supported in the substantive theory.

The only concept related to this model was when the respondents mentioned the patent law where national companies competed with multinationals. Pharmaceutical lobbying in Argentina was only carried out by one actor. It could have been the pharmaceutical industry as a whole, acting in a cooperative way, or it could have been the individual pharmaceutical company trying to influence an official. Even when a pharmapolitics manager tried to incorporate a product in the PMO (National Formulary) there was no other lobbying actor trying to hinder or counteract this action. This model did not consider when lobbies cooperated by bringing the same information to the official; it did not consider the cooperative lobbying found in the substantive theory.

Lohmann's (1993) analysis deviated from the basic communication model and it focused on the position of the official when he/she made a decision about a certain policy. In this model, there were a finite number of lobbying groups distributed along an interval. They were characterised by single peaked preferences about the policy in question and each group preferred the policy alternative which was closer to its ideal point. This model contained some elements that were found in the substantive theory but it did not correspond to the reality found in pharmaceutical lobbying as there was usually only one lobbying actor, which could have been the pharmaceutical industry or one company. The common elements found were the following:

- The official also had information about what the lobbying actor, in this case the pharmaceutical company, expected about a certain policy.
- It introduced the concept of the costs of getting the information that has to be presented to the official. The pharmaceutical company had to decide whether to incur in additional costs, of pharmaeconomic studies, if the information presented in the dossier was not enough.

These two elements were supported by the substantive theory; the pharmacopolitics manager expressed his/her expected policy so that the official had this information. The other issue was that the pharmaceutical company, when asked about more studies, especially local, had to decide whether to incur those additional costs.

This model also introduced the concept of moderates and extremists, which was similar to the model of good and bad lobbies. As noticed before, this moral classification was not found in the data gathered. The model also argued that only moderates would not always send information but that was not the case in pharmaceutical lobbying as information was always supplied.

Lagerlof (1997) extended this model and assumed that the interest group was imperfectly informed. The substantive theory showed that pharmaceutical companies had invested hundreds of million dollars in research and development and therefore the assumption that the lobbying actor was imperfectly informed was not valid to a certain extent. The researcher acknowledged that perfect information was not possible to achieve, but the pharmaceutical companies possessed the most complete information available regarding the product or technology. The pharmaceutical company was only forced to acquire additional information when the official expected it. This additional information was most of the time local pharmaeconomic models or studies.

Communication costs served as an access device that informed the officials about the benefits of granting access to certain groups. Lohmann (1995a) and Austen-Smith (1998) presented models where the interest groups and lobbying actors, in this case the pharmaceutical companies, gained access to officials via contributions. The substantive theory demonstrated that in Argentina no contribution had to be paid to obtain access. Access was facilitated by previous contacts or by another pharmacopolitics manager/free-

lance lobbyist, who, on rare occasions, collected a fee for performing the introduction. Therefore, this model did not apply to the substantive theory of pharmaceutical lobbying in Argentina.

The other channel of influence decisions were the contribution payments. Contributions provided incentives for the officials to deviate from the best policy choice. These models fully specified the objective function of both the official and the pharmaceutical company. This allowed for an analysis of strategic interaction between interest groups /lobbying actors and the official. The consideration that the researcher took on analysing the contribution payment models was that sometimes these contributions were aimed at HMOs and in other cases at the private interest of officials. The models of this section made use of theoretical results from common agency theory which comprised of situations in which a set of principals (pharmaceutical companies) influenced the decision of a common agent (officials).

Grossman and Helpman (1994) introduced the first lobbying application into the framework of the common agency theory. In this model the official decided a policy which affected the payoffs from the pharmaceutical companies who in turn try to influence his/her choice. In the first stage of the game each lobbying actor decided on a contribution offer to the official, or the HMO, stating how much money was to be paid for each alternative policy realisation. In the second stage the official observed these offers, determined the policy, and collected the respective money offers. It must be remarked that this model did not fit exactly in the substantive theory of pharmaceutical lobbying as the model implied that there were competing interests between lobbying actors. In pharmaceutical lobbying there could be different contingent offers but they would be for different objectives namely for different products. There was also the case where pharmaceutical companies acted in a cooperative way; the official had only one

offer. He/she had to decide simply whether to accept or to decline. Nevertheless, the model was helpful for the substantive theory as it provided a contribution payments framework stating how the pharmaceutical industry or the individual companies and officials interacted.

The official might well have preferences about the policy. For instance, a benevolent official would prefer the policy which maximised aggregate welfare for the HMO. Contribution offers by companies served to compensate the agent for any deviation from the welfare maximising policy. On the other hand, the official could be completely opportunistic and care only about contributions and not about the policy itself. In the substantive theory there was a mixed approach; officials frequently looked for a deviation of the policy that partially benefited the HMO and also partially benefited their private interests. This model introduced the contribution payments issues and provided the guidelines into which the substantive theory was grounded. This model did not consider the cooperation between companies, as described when the pharmaceutical industry had to lobby the government or big HMOs.

Rama and Tabellini (1998) stated that cooperative lobbying led to higher payoffs than non-cooperative lobbying. Particularly they analysed the case when there was one coalition lobbying the government compared to individuals with the same purpose. This abstract model depicts what happened in Argentina when lobbying the government as described in the substantive theory. If the government achieved a high payoff with any of the individual companies alone, it was able to play the companies against each other and benefited from a conflict of interest between them. In contrast if the joint payoff to a coalition of all players, the government and all companies, was high then there was an interest to include all relevant actors in the political process. The substantive theory indicated that pharmaceutical companies in Argentina cooperatively lobbied the

government or large HMOs to avoid being outplayed by these organisations. The payoffs for the coalition were higher than the payoffs of individual lobbying.

The common agency lobbying model presented by Grossman and Helpman (1994) only assumed a small country. This implied that the government set policy independently of possible countervailing measures by a foreign country and so strategic interaction between different countries played no role. Grossman and Helpman (1995), in another paper, extended the basic lobbying model to consider this aspect and studied strategic interaction between two governments. In the substantive theory, it was shown that the USA interacted in the Argentine scenario specifically regarding the medicine's patent law. The American government received the pressure of the American pharmaceutical industry through its chamber (PhRMA). This lobbying by PhRMA aimed to introduce changes in the patent law in Argentina. As the countries traded with each other there was a degree of pressure than could be exerted to influence the other government. In the patents law case the USA persuaded the Argentine government to introduce some changes suggested by PhRMA (the American pharmaceutical chamber). At that time the influence of the American Embassy over the government was high. Even then, the law was not exactly what the American government wanted. The Argentine government was no longer able to independently respond to lobbying activities but needed to take strategic interactions with the American government into account. This extension of Grossman and Helpman (1995) was supported by the substantive theory.

The literature on lobbying divided into two broad movements as the preceding sections indicated; either as contribution payments or as a means of transmitting information. The approach stated by Bannedsen and Feldmann (2001) was the only one that could describe pharmaceutical lobbying in Argentina. They introduced the first mixed approach with both components. Their new model focused on the instrument choice of

lobbying. They assumed that a lobbying actor, in this case a pharmaceutical company, could influence a political decision in two independent ways. Firstly, it could engage in costly information acquisition and transfer the result truthfully. In the case of the pharmaceutical companies the acquisition of costly information was essential as the information was needed for the registration of the product. Pharmaceutical companies communicated this information truthfully to the officials.

Secondly, the pharmaceutical company determined contribution payments that compensated the official or the HMO, or both, for a deviation towards its preferred policy choice. The question for Bennedsen and Feldmann (2001) arose when the company had to decide which type of lobbying the official preferred and how these instruments affected each other. That was also an uncertainty for the pharmapolitics managers when he/she approaches an official with whom he/she had no relationship. First, he/she would transmit information and later in the negotiation the pharmapolitics manager had to decide whether to turn to contribution payments.

Damania and Fredriksson (2000) focused on incentives to free-ride in a set-up where two lobbying actors followed a common interest. Each group might abstain from lobbying, lobby alone, or form a coalition with the other lobby. The authors stated conditions such free-riding on the other firm's lobbying activities, joint lobbying, or unilateral lobbying occurred in the state game. If the game was repeated infinitely, cooperation might result even if free-riding was the optimal behaviour in the state game. Cooperation was implemented through trigger strategies, which let each firm cooperate as long as the other one did. Cooperation was more likely if the short term benefit of defection was small relative to the discounted future benefits of cooperation.

The substantive theory demonstrated that free-riding, when occasionally occurred, was

strongly punished in the Argentine pharmaceutical market. First, the findings correlated with Damania and Fredriksson (2000) as companies did follow a common interest and they tended to lobby together in a cooperative way. The benefits of cooperation were much higher than those of free-riding. Additionally there were severe punishments for the companies that decided to free-ride. In these cases the pharmaceutical industry in Argentina had the authority and capacity to be coercive to its members. These punishments were the exclusion from the HMOs' formularies and from industry negotiations with the Government. The rational choice for companies was to adjust to the cooperative rules and form a coalition.

Mitra (1999) abstracted from incentives to free-ride within interest groups and presented another model. He extended the basic lobbying model and analysed the entry decision of interest groups and not the exit decision. This was supported by the substantive theory that showed that most companies decided to enter the lobbying coalition as the benefits of participation exceed the costs of entry.

6.2.3 Substantive theory and formal micro-theory of lobbying

The formal micro-theory of lobbying was reviewed only to describe the characteristics of the health care system and so that the reader can understand the different elements present in the substantive theory.

The term pharmacopolitics or pharmapolitics was defined as the activities performed by the pharmaceutical industry aimed at influencing government, public officials and Health Management Organisations (HMOs) in order to get a competitive advantage in the Market (Quiñones, 2002). The definition given by Quiñones was supported by the substantive theory. The motivations for pharmaceutical lobbying were not only aimed at gaining a competitive advantage in the market but also to increase sales, maintain

market share within the formularies, influence the officials in their decisions and build relationships to simplify future negotiations.

The researcher would like to briefly point out some differences between the two health care systems that were supported by the substantive theory.

Cooperative lobbying was carried out in both countries and was used to lobby the government and large HMOs. In both cases they used the Chamber as an instrument of cooperative lobbying. The difference in Argentina was that a coalition of companies- national and multinational- also lobbied the government and large HMOs. In the USA a coalition of companies lobbying together was not permitted so lobbying was carried out by the Chamber or by individual companies.

In both countries, the pharmaceutical industry was one of the most potent political forces when it came to influencing legislation in the government or large HMOs. There were no records in Argentina about how much money was invested in the pharmaceutical lobbying. Hiring of free-lance lobbyists was done occasionally in Argentina in those cases where the pharmacopolitics manager had no access to the official. In the USA it was a common practice.

The methodology of executing lobbying in Argentina differed to the USA. Respondents mentioned that there were no donations to campaign contributions. The financing of the ruling political party was generated by corruption in the health care system. The use of advocacy groups was not supported by the substantive theory. In both countries, there were close ties to the public officials. Lobbying was implemented by pharmacopolitics managers in Argentina. In the USA, lobbying of public officials was implemented through external lobbyists.

Pharmaceutical companies had the same motivations as in the USA except for the

pursuing of tax breaks in the legislation. Patents, increasing sales, maintaining share in the formularies, protecting against generic sales and preserving the freedom to establish prices were also motivations for lobbying in Argentina. The economic impact of lobbying in Argentina could not be identified in the substantive theory.

The HMO context was similar to the USA. There were multiple fragmented organisations that provided health care to a number of individuals. The objectives of these organisations were the same in both countries. The HMOs were organisations that contracted and supplied medical care on the basis of a fixed periodic payment; their activities were the management of medicines and treatment aimed at containing costs and promoting effectiveness. The different elements of the HMO setting were as follows:

- a) Restricted formularies: in both countries HMOs adopted the use of restricted formularies to contain costs. The principal objective of formularies was to bring down costs selecting a narrower choice of drugs and adopting generics to replace the highly-price brand-name products (Dranove, 2003). A high percentage of the Argentina population belonged to an HMO with a restricted formulary. The respondents mentioned that there were controls issued by the HMO to make sure that physicians complied with the formularies. Those controls did exist in the USA. The pharmaceutical industry in Argentina and the US cooperated with the design of disease management programmes.
- b) Pharmacy Benefit Management (PBM): in both countries, HMOs contracted PBMs for the management of pharmacies and the formulary. PBMs controlled costs by negotiating discounts from manufacturers, usually in the form of rebates, in return for placing the manufacturer's drug on the PBM formulary.

PBMs in Argentina selected participating pharmacists, groups of drug manufacturers and administered point of sale claims. As in the USA, PBMs were intermediaries between the pharmaceutical industry, the HMOs and the pharmacies. The difference between Argentina and the USA was that PBMs in Argentina had to negotiate rebates with a group of companies, a coalition, instead of individual companies. The pharmaceutical industry realised that cooperative negotiation was needed to achieve lower rebates and extended formularies; in this way pharmaceutical companies were able to introduce more expensive medications and in the case of multinationals, new products.

- c) Managed care account manager and pharmapolitics manager: The main difference between the managed care account manager and the pharmapolitics manager was that the pharmapolitics manager performed the lobbying not only to HMO and PBM officials but also to the government and public officials. The job was more comprehensive in Argentina as it was related to the total process of lobbying for a multinational company.
- d) Distrust: in both countries there was distrust by HMO officials towards the pharmapolitics manager or managed care account manager. This distrust was based on a conflict of interest where HMOs saw financial support from formulary positions being sold and this financial support also compromised objective pharmacy and therapeutic committee decisions. The pharmaceutical company's objective was to maximise sales in a formulary and the HMO wanted to contain costs and provide a better service to their affiliates. However, the pharmapolitics manager in Argentina built close relationships with HMOs officials and there was not an issue over lack of trust.

- e) Rebates: in both countries. There were two typical types of rebate offered to HMOs or PBMs: an access rebate and a market-share rebate. The difference between Argentina and the USA was that in Argentina the access rebate was usually a contribution payment to the official instead of the HMO while the market-share rebate was a contribution payment made to the HMO.
- f) Objectives of pharmapolitics activities: The inclusion of products in formularies was a controversial issue in the managed care setting even in Argentina. The reason why the pharmapolitics manager existed was that, although there should be an independent pharmacy and therapeutics committee to decide which products were included in a formulary with checks that none of the decision makers “inappropriately curry favour” (Studin, 2002, p.49), there was nonetheless the possibility of exerting influence on the inclusion decisions by HMOs. This influence was carried out through rebates, special agreements or other means such as hospitality, grants or programmes with key decision makers.

6.2.4 *Summary*

Formal theory of lobbying was discussed against the substantive theory described in the previous chapter. Firstly the inclusion of the pharmaceutical industry in the formal macro-theory, then an analysis was made of the definition of the role of the pharmaceutical industry as an interest group in the framework of pluralism, corporatism, meso-corporatism and corporate pluralism. The researcher also explored the interest group theory formation in the light of substantive theory.

Next the meso-theory of lobbying was explored. The two different approaches of lobbying, transmission of information and contribution payments, were then discussed.

Elements of both approaches were supported by the substantive theory. The approach that fitted best with the substantive theory was that of the mixed approach presented by Bennedsen and Feldmann (2001) - this stated that both approaches were used and the lobbying actor should decide which to use at a certain moment. Free-riding was also discussed and the substantive theory demonstrated that free-riding in the Argentine pharmaceutical industry was difficult because of the punishments imposed by other companies on the free-riders.

The micro-theory of lobbying was also summarised. The literature review considered only the literature of the USA as there was no relevant Argentine literature. The market was similar so it was pertinent to use the American literature. The discussion illustrated the similarities and differences in the application of pharmaceutical lobbying.

6.3 Conceptual findings

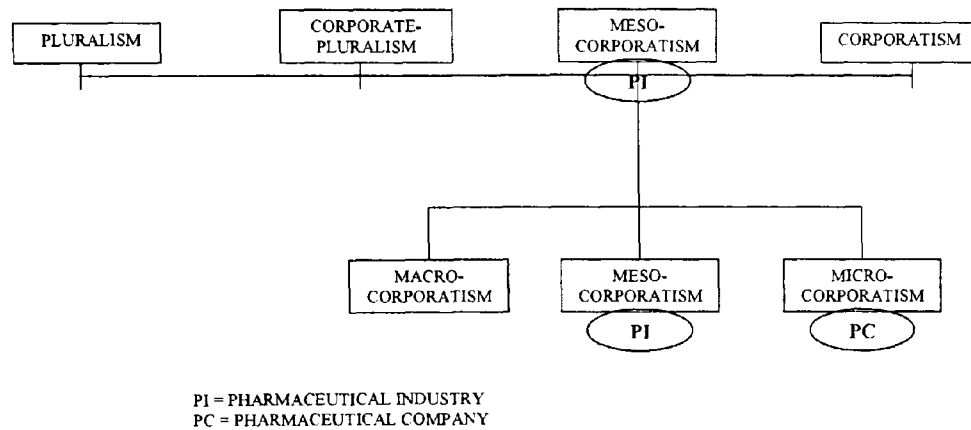
The research questions in this study aimed to address why and how pharmaceutical lobbying was carried out by pharmaceutical companies in Argentina. The substantive theory has dealt with both research questions extensively. Later, the discussion of the formal theory and substantive theory enabled the researcher to abstract from the substantive theory and through a deductive and intellectual processes develop the conceptual findings which provide new insights into the theory of lobbying. The researcher developed four new models which applied to the core category, **pharmaceutical lobbying** in Argentina. The models and insights are explained below:

6.3.1 Position of the pharmaceutical industry in the corporatism-pluralism scenario

Throughout the discussion with the formal macro-theory of lobbying it was explained that the Argentine pharmaceutical industry, as an interest group, was identified more with the corporatism theory than with the pluralism as it has a specially privileged relationship with the government. The pharmaceutical industry was also recognised by the state and granted a deliberate representational monopoly within its category. The pharmaceutical industry also cooperated with the government in the design of regulations that might affect its interests.

In an attempt to describe the position of the pharmaceutical industry in the pluralism-corporatism scenario, the researcher decided to take into account not only the original ideologies of pluralism and corporatism but also its variations of meso-corporatism and corporate-pluralism. The model identifies new insights in the lobbying theory as it describes the position of the pharmaceutical industry, the individual companies and their pharmacopolitics managers regarding these theories.

Figure 9 *Pharmaceutical industry in the pluralism-corporatism Axis*



The pharmaceutical industry fitted in the meso-corporatism approach as a collective actor that defended the specific interests of the pharmaceutical companies. As discussed in the previous section, the pharmaceutical industry as an interest group was not related to the concept of pluralism or corporate pluralism. Kelso's (1978) version of corporate pluralism was the closest to the pharmaceutical industry in the pluralist model; in his definition there were a series of autonomous fiefdoms presided over by interest groups which cooperate with the government, having an important role in decision-making. However, the researcher considered that meso-corporatism was the best fit for the pharmaceutical industry and the pharmaceutical companies as lobbying actors. In the meso-corporatism approach, the pharmaceutical industry was the peak association that influenced government about health care decisions.

Once positioned in meso-corporatism the researcher realised that there was a further classification to be made. Wassenberg (1982) established three different types of corporatism:

- a) Macro-corporatism: represented the peak institutions of the politico-economic body, e.g. congress.
- b) Meso-corporatism: considered the pharmaceutical industry directly lobbying congress and the government as a peak institution in its sector. In this research, the multinational companies chamber (CAEMe) occupied the role of peak institutions in its relationship with the government. Coalitions of companies could be also considered in the meso-corporatist concept.
- c) Micro-corporatism: This element was important as it best described the individual company in the lobbying process. The pharmaceutical company, through its pharmapolitics manager, influenced the officials at this level inducing them to make favourable decisions for the companies. Although Wassenberg (1982) classified the chambers as a part of the micro-corporatism model in this research they were part of the meso-corporatism model as they had a special relationship with the government.

This model explained the position of the pharmaceutical industry and its chamber as an interest group in the scenario of the different theories within the macro-theory of lobbying. It also positioned the pharmaceutical company as a lobbying actor in the corporatist model.

6.3.2 Pharmaceutical lobbying style

Lobbying cannot be understood without looking at the context in which the lobbying actors were trying to act. The model of Woll (2006), which depict the different styles of lobbying in the USA and in the EU, was adapted to show the pharmaceutical lobbying style in Argentina.

Figure 10 *Lobbying style model*

| | United States | European Union | Pharmaceutical Lobbying in Argentina |
|---|--|--|---|
| <i>Organization of interest representation: How do individual actors organize?</i> | Direct representation, issue-specific coalitions, which may take the form of longstanding associations | National and sectoral peak organizations, which tend to form European platforms, recently also direct representation | National (Chambers) and issue specific – coalitions. Also direct representation |
| <i>Instruments: What methods and resources are available?</i> | Financial contributions, legal representation, formal and informal consultation, media and grass-roots tactics | Mainly consultation, both formal and informal, some legal advice, outsider strategies limited | Financial contributions, formal and informal consultation, outside strategies limited |
| <i>Policy process target: Where and when do lobbyists decide to act?</i> | From contributing to the formulation, affecting revisions to blocking decision | Lobbying on formulation and revision at supranational level; decision lobbying pursued national route | Lobbying on formulation and revision of policies |
| <i>Characteristics of consultative lobbying: What kinds of relationships develop between public and private actors?</i> | Competitive, fragmented, both short term and long term | Long-term and trustbased, multi-level strategies | Long-term and trustbased. Personal relationships are encouraged |
| <i>Style of consultative lobbying: How do lobbyists express their demands?</i> | Defensive, direct, focus on immediate interests | Constructive, cautious, consensus-oriented | Direct, focus on immediate interests |

The organisation of interest representation in Argentina had three modalities: one was the national organisation- the Chamber of Multinational Companies (CAEMe) which lobbied the government and the large HMOs. The second was issue-specific coalitions

between a group of companies that also lobbied the large HMOs and the last modality was the direct lobbying of the individual company, oriented at HMOs and officials, in issues related specifically to the company's products. The pharmaceutical lobbying style in Argentina had in common with the American style the direct representation and issue-specific coalitions and it shared with the EU the representation of interests at a national level by national peak associations (CAEMe).

The instruments used by the three modalities (Chamber, coalitions or individual companies) of lobbying actors in Argentina were financial contributions in the form of payments to the HMO, to the official or both the HMO and official (Grossman and Helpman, 1994). The issue of consultation identified by Woll (2006) was interpreted by the researcher as transmission of information (Potters and van Winden, 1992 & Ainsworth, 1993). Lobbying actors met the officials and they consulted about specific issues. The lobbying actors expressed their views and provided information. In pharmaceutical lobbying in Argentina both instruments were used: contribution payments and transmission of information as in the model of Bannedsen and Feldman (2001). It also shared with the EU limited external lobbyists hiring.

Pharmacopolitics managers and the pharmaceutical industry acted before legislation was issued or the formulary developed. Lobbying was based in influencing the formulation of the new policy. Lobbying was also carried out to change existing policy in favour of the pharmaceutical industry (e.g. the reference prices decree mentioned in the substantive theory) or to introduce the company's product in the formulary at an individual level.

The relationship between the pharmacopolitics managers and the officials tended to be long-term, not issue oriented and based on reciprocity. In the substantive theory, this

concept was developed in the building trust concept. Relationships between officials and pharmacopolitics managers were encouraged.

The answer to the question of how lobbyists expressed their demands was in a direct way. Most of the time there was an existing relationship between the lobbying actor and the official so the demand was direct, focusing on immediate interests. It differed from the EU style that was cautious and consensus-oriented.

The lobbying style model demonstrated that pharmaceutical lobbying in Argentina was different to that of the USA and EU although it shared common features with both of them. This model could be used by other researchers in Argentina to find out whether the model is applicable to other industries.

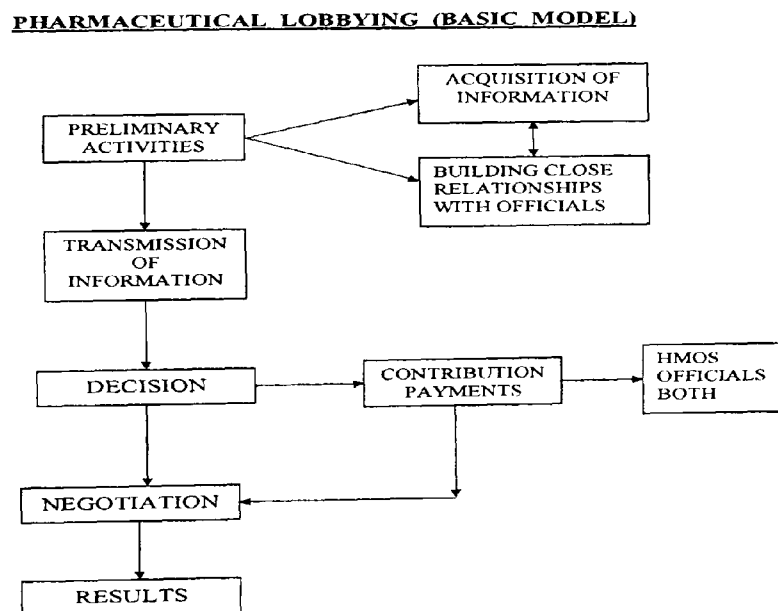
6.3.3 Pharmaceutical lobbying process model

This model was based on the meso-theory of lobbying. In this theory, there were only two channels of influence: transmission of information and contribution payments. All the literature based on the game theory considered either one channel of influence or another; the only model that considered a mixed approach was presented by Bennedsen and Feldmann (2001). The model developed in this research for pharmaceutical lobbying introduces two elements, which differed from the traditional approaches in the meso-theory of lobbying:

- a) Firstly there was a preliminary process before the transmission of information and/or contribution payments which was not considered in the traditional meso-theory of lobbying. This preliminary process should be included in the process as it was part of it and conditioned the role of the participants in the process.

b) Secondly there was always transmission of information. It differed from the approach of Bennedsen and Feldmann (2001) who stated that the lobbyist should decide which approach to be used based on the expected outcomes. In this model, pharmapolitics managers always transmitted information independent of the expected outcomes; this transmission of information could occur with contribution payments or without. The difference in pharmaceutical lobbying was that the information had been acquired, for registration purposes, before the lobbying process began. The pharmaceutical companies needed the information for registration purposes and the information was always available for the pharmapolitics manager. The following is the model of pharmaceutical lobbying in Argentina.

Figure 11 *Pharmaceutical lobbying model*



6.3.3:1 Preliminary activities

- a) Acquisition of information: The process of registering pharmaceutical products entailed the acquisition of costly information by the pharmaceutical company. As the cost of information acquisition for the pharmapolitics manager was small or non-existent, a policy of transmitting information was preferred. If the official asked for additional information it was likely that this information already existed. Only local pharmaeconomic studies resulted in an additional cost. The pharmaceutical lobbying model was different from the one presented by Bennedsen and Feldmann (2001); in the latter the lobbyist should know the interests of the official because any option - transmitting information or contribution payments - had a cost. In the case of pharmaceutical lobbying, the only cost for the pharmapolitics manager was contribution payments.
- b) Building trust: This element was not mentioned in the meso-theory of lobbying. The meso-theory models assumed that the different interest groups had the same possibilities regarding the official in their lobbying process. The model in this research considered there was a difference when the lobbyist had close ties with the official. Bargaining power was different; in the lobbying game some companies had more influence on the key officials than others. Pharmaceutical companies in Argentina did compete for the attention of the official even if they did not compete for formulary positions. The official, on deciding which product from a list of five to introduce first, would choose the product from the pharmapolitics manager with whom he/she had the closest relationship. Therefore, there were some companies with a stronger position and others with a weaker position at the beginning of the lobbying game because of the building trust process.

6.3.3:2 Transmission of information

Information was always supplied to the official during the pharmaceutical lobbying process in Argentina. This transmission of information had caused the official to always expect the receipt of a dossier about the product or the new technology. When he/she did not receive information he/she assumed that the product or technology was not worth considering. The substantive theory chapter said that in those cases where there was no scientific information available the pharmapolitics manager had to use other instruments i.e. contribution payments. In cases when the official expected only transmission of information and he/she was not amenable to contribution payments the lobbying process would fail due to lack of scientific evidence. The company had to decide whether to acquire this costly information or give up the objective pursued. Transmission of information was the means by which the pharmapolitics manager initiated the lobbying process. The official took into account the information received and then decided whether this information was enough or, if he/she expected a contribution payment, would wait for the negotiation phase.

6.3.3:3 Decision

This part was dealt with in the substantive theory chapter. The pharmapolitics manager had to decide whether to continue with transmission of information or switch to contribution payments. After the decision of which of the two channels of influence was to be used the pharmapolitics manager began the negotiation process.

6.3.3:4 Negotiation

Negotiation always began after the submission of information. There was an iterative process, which could follow the channel of transmission of information, of the official asking for more information and the pharmapolitics manager providing more

information until the official was satisfied and accepted the request of the pharmapolitics manager. In this case the official maximised aggregate welfare for the HMO or the government. It also maximised the utility of the pharmaceutical company as there was no additional cost for achieving its objectives. Alternatively the process could lead to a contribution payments situation and the pharmapolitics manager had to estimate which offer would be acceptable for the official. The pharmapolitics manager had to discover whether the official was opportunistic and only looking for his/her private interest or if he/she was seeking to benefit the HMO. The model of Bennedsen and Feldmann (2001) stated that the question arose when the company had to decide which type of lobbying the official preferred. There were three possibilities: rebate for the HMO, payment to the official or as stated in the substantive theory a mixed payment with a rebate for the HMO and a contribution payment for the official. The first issue was to find out which was appropriate and then negotiation took place. According to the substantive theory and supported by the formal meso-theory, the pharmapolitics manager made an offer and the official had to decide whether to accept it or not. There was an interaction between offers until an acceptable agreement was reached. The pharmapolitics manager formalised the agreement and obtained a result.

This model can be applied to individual lobbying and cooperative lobbying. In the case of cooperative lobbying, the process was the same. The pharmaceutical industry initiated the lobbying process by obtaining information about the issue. The difference here was that the information was provided by the chambers or by a group of companies. Once the information was prepared in a dossier then the chamber official or the pharmapolitics manager with the closest relationship to the government or HMO official supplied the relevant information. The official evaluated it and might consider asking for more information. The process continued until the official had enough information to take a decision or the Chamber Manager decided to open the contribution

payments channel. After that, the negotiations on the theme of contribution payments continued until an agreement was reached; the agreement was formalised with either a rebate for the HMO, a contribution payment for the official or both.

This model based on the formal meso-theory of lobbying incorporated the substantive theory and synthesised the different elements of pharmaceutical lobbying in Argentina. This conceptual model can be tested on the pharmaceutical industry in other countries to establish whether it fits in different contexts.

6.3.4 Cooperative and individual lobbying

Cooperative lobbying was described in the substantive theory chapter addressing question eleven and was mentioned in the meso-theory of lobbying by Damania and Fredriksson (2000), Howell (2004) Aidt (1997), Graziano (2001), Hula (1999) and Hojnacki (1997) and Almeida (2005). Cooperative lobbying consisted of companies joining together to form a coalition for a specific purpose. Companies in Argentina preferred to lobby together when the target for lobbying was the government or the large HMOs. This was to avoid being played off against each other or their opponents benefiting from conflict of interests between them. A coalition had more political power than an individual company. Consequently, in Argentina, the cooperative approach was preferred for lobbying of government or large HMOs such as PAMI (the HMO of pensioners). However, it was also mentioned by pharmapolitics managers that, frequently, cooperative lobbying did not attend the interests of individual companies. Therefore, they also had to lobby the government and the large HMOs after the cooperative negotiation took place regarding specific interests of their companies. The following model shows this interaction between pharmapolitics managers and the government and large HMOs. Even if a cooperative agreement was achieved with the

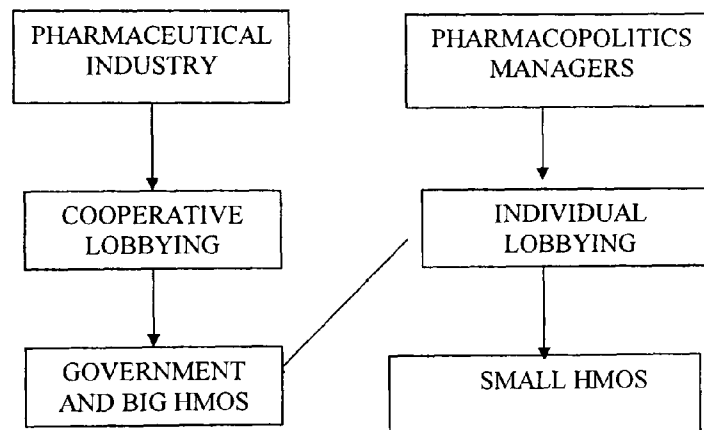
whole industry the official could make minor changes that would benefit one individual company.

In the cases of small HMOs individual lobbying was necessary. This was the job of pharmapolitics managers. They had to lobby these organisations to try to generate better business conditions for the company.

The following figure depicts the model of cooperative and individual lobbying.

Figure 12 *Corporate and individual lobbying strategy*

COOPERATIVE AND INDIVIDUAL LOBBYING



The pharmaceutical industry had two ways of lobbying depending on the lobbying target. If the target were the government and the large HMOs, the lobbying was cooperative. Even then there might be an individual lobbying to government or large HMOs in minor issues. If the targets were the other HMOs the lobbying was individual, carried out by the pharmacopolitics manager.

The researcher has presented the conceptual findings of this research. Four models were

developed: the position of the pharmaceutical industry in the corporatism-pluralism scenario, the lobbying style model, the pharmaceutical lobbying process and the cooperative and individual lobbying strategy. The first two models were based on the formal macro-theory of lobbying and the second two models on the formal meso-theory of lobbying. The models were grounded in the substantive theory and fitted with the lobbying exerted by the multinational pharmaceutical industry in Argentina. Within this context, the models can be analytically generalised. The generalisation of these models to other contexts or countries should be researched.

6.4 *Limitations of the Research*

The limitations of the research – using grounded theory methodology – manifested itself in a limited reliability and generalisation of the data and consequently of the conclusions drawn from the data. The researcher took a grounded theory approach with constant comparisons of the data and the findings with the aim of diminishing subjectivity in the research but there was always a degree of subjectivity in the interpretation of the data, that reflected the “self of the researcher”. It was unlikely that another researcher would have come up with the same categories and concepts to explain how pharmaceutical lobbying was carried out.

The choice of theoretical concepts in this study was arbitrary, using three different perspectives of lobbying theory to approach the different elements of the research object. The choice of lobbying theories was highly personal and subjective, yet justifiable in the context of grounded theory research. However, after the development of the research design, the research questions and the fixed set of questions it was unlikely that another researcher using the same sample of participants would have gained results contrary to these findings.

Another limitation of the study was its confinement to the reality of pharmaceutical lobbying in Argentina carried out by multinational companies. The theory developed in this study cannot be generalised to other contexts or to other countries. The substantive theory developed was only related to the context in which it was researched. Probably the biggest weakness of the research was the limited generalisation of the findings.

6.5 *Reflexivity considerations*

The advantage of the researcher studying his own culture from the inside was the possibility of being a direct source of information and interpretation. On the other hand, it brought the need for reflexivity when the researcher's own perspectives could have affected the research and the substantive theory being developed. The researcher had to reflect critically on 'self' within the research process because the study entailed the interpretation of complex interactions; it was important to guard against the possible effects of subjectivity during the research process. Being the inquirer in all cases, the researcher had to come to terms not only with those with whom he engaged in the interviews but with his position in the research setting. The researcher realised that there were different considerations of 'self' to be taken into account in both the interviews and in the interpretation of the data.

Firstly, the researcher identified his position as a colleague of the pharmacopolitics managers being interviewed. Trust existed between the researcher and his colleagues but the researcher realised that he had to maintain some distance when conducting the interviews as, during those moments, he was the interviewer. It was unusual for both, the interviewer and interviewee, as it was a new situation. The process of them giving written consent and the recording of the interview made the situation more formal. The same occurred in the interviews with the external lobbyists although, as the relationship

between the researcher and those respondents was not as close, the distance imposed was more natural. The interviews with the officials showed other peculiarities. They usually saw the researcher as lobbyist representing the interests of the company he worked for; his image was that of somebody who was always lobbying them for a certain purpose. The researcher felt that it was difficult for them to see a researcher who was investigating the lobbying process between them. The researcher had to reflect on how to conduct the interviews so that officials expressed their views about the lobbying process.

Another researcher's 'self' to be considered was the researcher as an interviewer. The researcher's familiarity with the subject and with the participants led the participants to make certain assumptions and express comments like "well, you know what I mean" (Interviewee B, PH). In those moments the researcher had to recognise that he was the interviewer and, although he did know what they meant, to ask for an explanation of the concept and to follow the rigours of the research. However, reflexivity also pertained to the 'self' as an interpreter. There were subtle meanings underneath the responses and the researcher had to interpret the meaning but without trying to introduce his previous beliefs or opinions. Reflexivity about 'self' was also present in the analysis stage. Interpretation and analysis might always be prone to subjectivity. The researcher tried to diminish subjectivity by reflecting on his own beliefs and trying not to introduce them in the analysis of the data. He performed iterative and constant comparison, focused on the data and the relationship of the different concepts, conditions, dimensions, properties, actions and interactions aimed at diminishing subjectivity. The researcher always tried to avoid subjectivity but has to admit that a certain degree of subjectivity and bias may always be present. The researcher realised this during the DBA; reflexivity was an issue as the researcher was, by definition, immersed in his own

culture.

6.6 *Future research*

The reason why the researcher decided to follow a grounded theory and not a game theory approach was the realisation that he was taking an analytic approach to understand a few controlled variables and a systemic approach should be taken for a deeper understanding of the interaction of variables in a complex environment. The researcher now has a deeper understanding of the pharmaceutical lobbying process in Argentina. The researcher identified the main variables to be taken into account in the process. The researcher plans to develop a game theory model of pharmaceutical lobbying in Argentina after refreshing his awareness of mathematical concepts. Once the model is developed and tested the objective of the researcher is to write and publish a paper.

Another issue that the researcher would like to explore in the future is a comparison between the pharmaceutical lobbying carried out in the UK compared to that of Argentina. The aim would be to understand the differences and similarities between the UK where health care is considered a social good and Argentina where it is a private good. This research would aim to extend the micro-theory of lobbying.

Corruption and its rational has been discussed by numerous authors but it was not an objective of this study, which only focused on the implementation of lobbying not on its moral consequences. The researcher has no immediate plans to develop any research related to corruption and its implications. The author recognises that the observation that no respondent talked about corruption, but rather about contribution payments, could be discussed within a linguistic research question and on a much larger platform within linguistic theory.

6.7 *Reflections on my intellectual journey*

I decided to take the DBA as its philosophy of being an active participant in the research process was the most appropriate for my personal situation. I had to interact continually, as a researcher, with the pharmaceutical lobbying world and I was central to the process of research. Through understanding specific situations, and in relation to more general concepts, I was able to make certain theoretical inferences and deal with practical problems. I tried to link the practice and theory of lobbying in a mediating discourse provided by the grounded theory methodology used in this research. The research process helped me to shift from a situation of empiric knowledge to one of theoretical knowledge, improving my professional practice as a pharmacopolitics manager. The interaction between theory and practice, through a mediating discourse, empowered me in terms of understanding lobbying strategies and helped to improve my work and to achieve my company's objectives. As a consequence of the research process, I modified aspects of my practice, behaviour and way of viewing and interpreting the process of pharmaceutical lobbying. I learned from case to case about my role as a lobbyist as well as the successes and failures that will guide the way I perform my job in the future in all relevant and maybe less relevant aspects of my role. While I have learned more about lobbying and the art of influencing people, I also learned how to conduct a research project. This study extended my knowledge and will contribute to the development of theory. The kind of theory developed is grounded in my professional practice. The theory developed in this study will be the starting point when I begin further research with an equal or similar purpose.

Studying a doctorate has been an intellectual process where change was an always present element. Firstly, a change of supervisor at the beginning of the doctoral process. A new supervisor meant a change of approach. Later on my supervisor changed

university and I followed him all the way to Glamorgan. Darwin discovered that the species that survive were those that adapted to new situations and contexts. I had to adapt to all these changes and I emerged stronger than before.

Secondly, I changed my methodology four times- beginning with a quantitative Bayesian approach and ending with a grounded theory approach. This helped me in the research learning process as I had to first learn the quantitative and then phenomenological methodologies. I consider that I now have a deeper understanding of different methodologies for my future research and am not confined to a certain type of methodology but to a broader choice.

Thirdly, I changed my lobbying strategies based on the formal theory of lobbying. In my job I can identify situations like cooperative lobbying and act following a certain strategy. As I mentioned before, it is putting theoretical knowledge into practice. The findings of the research have contributed to my own understanding in my role as a pharmacopolitics manager for a multinational pharmaceutical company. The research process has helped me to move from a position of empirical understanding to one of theoretical knowledge, which should improve my professional practice as a pharmacopolitics manager.

And lastly, but not related to change, I realised that persistence is one of the most required skills for everything in life. At the beginning, we were 40 candidates and after four years only three of us remain. It is not the brightest who reaches the goal, but the one who persists.

6.8 *Contribution to knowledge*

The research findings add to an existing body of knowledge- there has been research on pharmaceutical lobbying in other countries- as there had been no systematic review of how multinational pharmaceutical companies in Argentina undertake this process. The substantive theory will contribute to the general knowledge of lobbying and provide a deeper understanding of how pharmaceutical lobbying is carried out in Argentina

The first model of the position of the pharmaceutical industry in the corporatism-pluralism scenario extended the knowledge of those theories but specially that of meso-corporatism by identifying the pharmaceutical industry in Argentina as an interest group that fitted in the meso-corporatist model. The researcher also identified the position of the pharmaceutical companies in Argentina as lobbying actors in the micro-corporatist model presented by Wassenberg (1982).

The second model of the pharmaceutical lobbying style extended the model presented by Woll (2006) by comparing the pharmaceutical lobbying styles of the EU and the USA to those of Argentina. The author identified elements from both styles (EU and USA) present in Argentina but with sufficient differences to signify a new style.

The third model of the pharmaceutical lobbying process model refuted the meso-theory of lobbying that one of the two channels of influence should be used, either transmission of information or contribution payments. The model was also different to that of Bennedsen and Feldman (2001) as transmission of information was always used irrespective of the future lobbying strategy. This model refuted the theory that contribution payments for transmission of information should be used as substitutes and shares with Bennedsen and Feldman (2001) the logic that both instruments could be used together. Another distinct element was that building trust was introduced as a key

factor for success. Building trust as a concept was ignored in the meso-theory lobbying models.

The fourth model corroborated the meso-theory of lobbying that when the government represented the official (Rama and Tabellini, 1998), lobbying in a coalition was better than lobbying alone. The model extended Rama and Tabellini's model because it introduced the large HMOs as a target for cooperative lobbying. The model introduced the additional concept of cooperative lobbying not attending the specific interests of individual companies and companies then individually lobbying the government or large HMOs. This model also described the lobbying target for individual companies.

The emergent theory contributed to the body of knowledge concerning lobbying theory. The models and substantive theory developed in this research could be tested in other industries within the country or in the same industry in other countries. This study recognises, from the perspective of the pharmaceutical industry, that lobbying has occupied an important role within the companies and that resources were allocated and will continue to be allocated for this purpose.

6.9 Conclusion

Theory emerging from the collection and analysis of data, according to the central tenets of grounded theory, could indeed be grounded in the broad field of lobbying theory. Substantive theory emerged from the researcher's grappling with not only his own analytical perceptions but from empathising the ways in which respondents themselves constructed their world. Emerging concepts were subjected to repeated coding, confirmation of observations from multiple data sources, theoretical elaboration from interpretations of these multiple sources and continual testing for consistency across different perspectives. In this developmental process, concepts were identified,

developed and merged in order to produce the component elements of substantive lobbying theory. The researcher chose grounded theory because he could commence from a specific 'grounded in reality' event, pharmaceutical lobbying, with the intent of understanding the nature and rationale of observed incidents. Inductive theory generation was embedded in explanation of pharmaceutical lobbying, rather than generalities or broad statements. Pharmaceutical lobbying is as a broad concept, dynamic and interactive by nature, and grounded theory had the inductive capacity to scrutinise data and offer subsequent theories on such subjects. Grounded theory developed predictive ability - to explain what happens in the context of pharmaceutical lobbying. The two research questions "why" and "how" pharmaceutical companies carry out lobbying were addressed and substantive theory built. The theoretical sampling frame was designed as wide as possible so that the theory became embedded in reality. Triangulation of sources enhanced the consistency of the findings, consolidating the internal validity. Three research quality criteria were applied: construct validity, internal validity, and external validity. Strict operational procedures supported the construct validity. Implementing grounded theory methodology supported the internal validity. The comparison of the substantive theory against the existing conceptual frameworks documented in the formal theory of lobbying enabled the researcher to develop the conceptual findings and supported the external validity of the research. Formal theory was applied initially to help formulate questions for the respondents. The interviewees' practical knowledge was analysed and the theoretical framework constructed in order to look for saturation across cases. A grounded theory approach allowed the formulation of substantive theory in the field of pharmaceutical lobbying.

References

- Aaron, C (2004), The Medicare Drug War. *Public Citizen Congress Watch Publications*, June 2004, pp. 1-44. 69, 70, 71, 72, 76, 79, 138, 139
- Adams C A (2004), The ethical, social and enviromental reporting-performance portrayal gap. *Accounting, Auditing & Accountability Journal*, Vol. 17 No. 5, pp. 731-757..... 18
- Aidt T S (1997), Cooperative Lobbying and Endogenous Trade Policy. *Public Choice*, Vol. 94 pp.455-475. 51, 140, 253
- Aidt T S (1998), Political Internalization of Economic Externalities and Enviromental Policy. *Journal of Public Economics*, Vol. 69 (1) pp.1-16. 49
- Ainsworth S (1993), Regulating lobbyists and interest group influence, *Journal of Politics*, Vol. 55 pp. 41-56..... 16, 56, 90, 138, 139, 230, 247
- Almond G (1983), Corporatism, Pluralism and professional memory. *World Politics*, Vol. 35, pp.245-260..... 37
- Arrow K J (2004). *Is Bounded Rationality Unboundedly Rational? Some Ruminations*. Cambridge: MIT Press 56
- ASI Solutions (2002), <www.asi-solutions.com, 2/08/03>..... 84
- Atkinson P & Hammersley M (1998), Etnography and Participant Observation, in Denzin N K & Lincoln Y S, *Strategies of qualitative Inquiry*, Thousand Oaks, Sage..... 105
- Aumann R (1997), Rationality and Bounded Rationality. *Games and Economic Behaviour*, Vol.21, pp.2-14..... 55, 56
- Austen-Smith D (1998), Allocating Access for Information and Contributions. *Journal of Law, Economics, and Organization*, Vol 14 (2) pp. 277-303..... 16, 60, 61, 90, 92, 232
- Austen-Smith D and Wright J R (1992), Competitive Lobbying for a Legislator's Vote, *Social Choice and Welfare*, Vol 9 (3) pp.229-257..... 16, 57, 58, 61, 90, 92, 139, 140, 230
- Axelrod R M (1984), *The evolution of Cooperation*. New York: Basic books. 189
- Bachrach P & Baratz M S (1962), Two faces of Power, *American Political Science Review*. December 1962, Vol. 56, Issue 4, pp.947-952..... 33
- Bailey K D (1994), *Methods of Social Research*. 4th Edition, New York: The Free Press 129
- Baldwin R E & Robert Nicoud F (2002), Entry and Asymmetric Lobbying: Why Government pick Losers. *Working Paper 8756, National Bureau of Economic Research*, pp1-23. 54

| | |
|---|--|
| Barker J A (1992), <i>Paradigms</i> . New York: Harper Business. | 97 |
| Becker G (1985), Public Policies, Pressure Groups and Dead Weight costs. <i>Journal of Public Economics</i> , Vol. 28 pp.329-347..... | 48 |
| Becker G S (1983), A Theory of Competition among Pressure Groups for Political Influence, <i>Quarterly Journal of Economics</i> , Vol 143 pp.371-400..... | 41, 48, 229 |
| Bennedsen M and Feldmann S E (2001). Informational Lobbying and Political Contributions. <i>CEBR Publications</i> . Discussion paper No. 2001-13, pp. 1-34. < www.cebr.dk/publications 2/4/04 >. 16, 47, 61, 90, 92, 138, 139, 235, 236, 242, 247, 248, 249, 250, 252, 261 | |
| Bentley A F (1967), The Process of Government. In <i>Pressure Groups</i> , Richarson J J. Oxford: Oxford University Press..... | 32 |
| Bernheim B and Whinston M D (1986b), Menu Auctions, Resource Allocation, And Economic Influence. <i>Quarterly Journal of Economics</i> , Vol 51 (1) pp. 1-31. | 49 |
| Bernheim B D and Whinston M D (1986), Common Agency. <i>Econometrica</i> , Vol. 54, pp. 923-942..... | 49 |
| Bouwen P (2002), Corporative lobbying in the European Union: the logic of access. <i>Journal of European Public Policy</i> , Vol. 9 (3), 365-390..... | 44 |
| Brown C (2001), Kant: an overview. <i>Trinity University Working paper</i> , < www.trinity.edu/cbrown/modern/kant.html , 11/03/05>..... | 96 |
| Browne W (1990), Organized Interests and Their Issue Niches: A Search for Pluralism in a Policy Domain. <i>Journal of Politics</i> , Vol. 52 (2), pp.477-509..... | 30, 32, 41 |
| Butin et al (2005), Rational Conduct, Fairness and Reciprocity in Economic Transaction Process. <i>Journal of American Academy of Business</i> , Vol. 7 (1), pp.338-353..... | 189 |
| Carroll J (2002), When success sours: PBMs under scrutiny. <i>Managed Care</i> , September 2002, pp.1-6.. 86, 87, 88 | |
| Cawson A (1985), Introduction: Varieties of Corporatism: The importance of the Meso-Level of Interest Intermediation. <i>Organized Interests and the State</i> . London: Sage | 35, 36, 37, 38, 89, 223 |
| Cerasale V. (2001), Farmacoeconomía Aplicada. <i>Revista Médicos</i> , Buenos Aires (Argentina), Año IV, No. XX, pp.72-74. | 66 |
| Clemente F, Greener A, Peck B, Benore A, Young B and Surrusco M, America's Other Drug Problem: A Briefing Book on the Rx Drug Debate. <i>Public Citizen Congress Watch Publications</i> , July 2002, pp. 1-81..... | 69, 72, 73, 74, 75, 76, 77, 78, 79, 90, 138, 139 |

| | |
|--|-----------------------------------|
| Coakley J & Gallagher M (1999), <i>Politics in the republic of Ireland</i> . 3 rd Edition, London: Routledge and PSAI Press..... | 29 |
| Coen D (1997), The evolution of the large firms as a political actor in the EU. <i>Journal of European Public Policy</i> , Vol. 4 (1), pp.91-108..... | 14, 43, 89, 227 |
| Common Cause (2004), Democracy on Drugs, The Medicare/Prescription Drug Bill: A Study in How Government Shouldn't Work.Holding Power Accountable Series, <i>Common Cause</i> , pp.1-8..... | 69 |
| Connolly W E (1969), <i>The bias of Pluralism</i> . New York: Atherton Press..... | 28 |
| Corporate Watch (2003), The Association of the British Pharmaceutical Industry (ABPI), A Corporate Profile. <www.corporatewatch.org.uk, 28/01/07>..... | 18 |
| Cox A (1988), The Old and New Testament of Corporatism: Is it a Political Form or a Method of Policy Making? <i>Political Studies</i> , Vol. 36, pp.294-308. | 31, 89 |
| Creswell J W (1994), <i>Research Design: Qualitative and Quantitative Approaches</i> . London: Sage 108, 109 | |
| Crombez C (2002), Information, lobbying and the legislative process in the EU. <i>European Union Politics</i> , Vol. 3 (1), pp.7-32. | 43 |
| Cross M (2005), Transparency Catches Eye in Coalition's Deal with Medco, <i>Managed Care Magazine</i> , March 2005, pp.1-4..... | 87 |
| Crouch C (1983), Pluralism and the new corporatism: a rejoinder. <i>Political Studies</i> , Vol. 31, pp.452-460. | 36, 37, 89, 222 |
| Dahl R (1984), Polyarchy, Pluralism and Scale. <i>Scandinavian Political Studies</i> , Vol 7 (4), pp.225-240..... | 29, 30 |
| Dahl R A & Lindblom C E (1976), <i>Politics, Economics and Welfare</i> . New York: Harper & Row... 33, 221 | |
| Dahl R A (1956), <i>A preface of democratic Theory</i> . Chicago: Chicago University Press..... | 28, 29, 33, 88 |
| Dahl R A (1961), <i>Who governs?</i> New Haven, Connecticut: Yale University Press | 32 |
| Dahl R A (1991), <i>Modern Political Analysis</i> . 5th. Edition, New Jersey: Prentice Hall Foundations of Modern Political Science Series. | 89, 221 |
| Damania R and Fredriksson P G (2000), On the formation of Industry Lobby Groups. <i>Journal of Economic Behaviour and Organization</i> , Vol. 41, pp. 315-336. | 15, 54, 61, 90, 92, 236, 237, 253 |
| Descartes R (1637), <i>Discourse on Method of rightly conducting the reason , and seeking truth in the Sciences</i> , Project Gutenberg. | 95 |

| | |
|--|-----------------------------------|
| Diesing P (1972) <i>Patterns of Discovery in the Social Sciences</i> . London: Routledge and Kegan..... | 26 |
| Dixit, A (1996). Special-Interest Lobbying and Endogenous Commodity Taxation. <i>Eastern Economic Journal</i> , Vol 22 (4), pp.375-388..... | 51, 52, 53 |
| Dranove D (2003), Determinants of HMO Formulary Adoption Decisions, <i>Working Paper Northwestern University</i> , pp.1-32 | 65, 82, 83, 85, 88, 91, 138, 239 |
| Easterby-Smith M, Thorpe R , Lowe A (1991), <i>Management Research: An Introduction</i> . London: Sage | 108 |
| Eisenhardt K & Bourgeois III L J (1988), Politics of Strategic Decision Making in high-velocity environments: Toward a midrange theory. <i>Academy of Management Journal</i> , Vol. 31, No.4, 737-770. | 12 |
| Eisenhardt K M (1989), Building Theories from Case Study Research. <i>Academy of Management Review</i> , Oct 1989; 14, 4 pp.532-550..... | 105 |
| Eising R (2004), Multilevel governance and business interests in the European Union. <i>Governance</i> , Vol. 17 (2), pp.211-246. | 44 |
| Evans B J & Taylor A J (2001), The rise of the Intermediate Level Institution in British Public Administration: The Case of Arts and Training. <i>Public Administration</i> , Vol. 72, pp.551-572..... | 38 |
| Fehr E & Gächter S (2000), Fairness and Retaliation: The Economics of Reciprocity. <i>Journal of Economic Perspectives</i> , Vol. 14, pp.159-181..... | 189 |
| Field R (2001), Introducing Kant's Epistemology, <i>The American Philosophical Association</i> , February 2001,< www.apa.udel.edu/apa/governance/committees , 02/03/05 > | 95, 96 |
| Fons J (2002), Comentarios Iniciales. <i>Demanda y Acceso a los Medicamentos</i> , C Vasallo and MB Sellanes. Buenos Aires: Observatorio de Salud, 2002..... | 86 |
| Top Performing Industries (2001), <i>Fortune Magazine</i> , April 2001, Vol. 127, pp.198 | 78, 79 |
| Glabman M (2004), Wish List: 10 things you want from your PBM, <i>Managed Care Magazine</i> July 2004, pp.1-9..... | 87, 138, 139 |
| Glaser B & Strauss A (1967), <i>The discovery of Grounded Theory - Strategies for Qualitative Research</i> . London: Weiferld and Nicolson. | 106, 107, 112 |
| Glaser B (1978), <i>Theoretical Sensitivity</i> . California: Sociology Press..... | 147 |
| Glaser B (1992), <i>Basics of Grounded Theory Analysis</i> . California: Sociology Press. | 106, 107, 110, 112, 113, 114, 122 |

| | |
|--|--|
| Goulding C (1999), Consumer research, interpretive paradigms and methodological ambiguities. <i>European Journal of Marketing</i> . Vol. 33 No. 9/10, 1999, pp. 859-873. | 103 |
| Goulding C (2002), <i>Grounded Theory: A practical Guide for Management. Business and Market Researchers</i> . London: Sage. | 154 |
| Grant W (1989) <i>Pressure Groups, Politics and Democracy in Britain</i> . London: Phillip Alan. | 28, 33, 37, 44, 68 |
| Grant W (2002), <i>Economic Policy in Britain</i> . Contemporary Political Studies. Hampshire: Palgrave. | 33, 43 |
| Graziano L (2001), <i>Lobbying, Pluralism and Democracy (Advances in Political Science)</i> . Hampshire: Palgrave MacMillan. | 52, 140, 253 |
| Grossman G M & Helpman E (1994), Protection for Sale. <i>American Economic Review</i> , Vol. 84 (4), pp. 833-850. | 10, 15, 49, 50, 51, 52, 61, 70, 84, 86, 90, 92, 138, 139, 140, 233, 235, 247 |
| Grossman G M and Helpman E (1995), Trade Wars and Trade Talks. <i>Journal of Political Economy</i> , Vol. 103 (4), pp. 675-708. | 10, 15, 51, 52, 61, 90, 92, 138, 139, 140, 235 |
| Guba E G and Lincoln Y S (1981). <i>Effective evaluation</i> . San Francisco: Jossey-Bass. | 129 |
| Guba E G and Lincoln Y S (2001), Paradigmatic Controversies, Contradictions, and Emerging Influences. In <i>Handbook of Qualitative Research</i> , Denzin & Lincoln. Thousand Oaks: Sage. | 98, 99, 100, 101, 103, 109, 118, 129, 256 |
| Gummesson E (2000), <i>Qualitative Methods in Management Research</i> . Revised Edition, Thousand Oaks: Sage. | 104 |
| Heisler M O and Kvavik R B (1974), Patterns of European Politics: The European Polity. In <i>Politics in Europe</i> , Heisler M O, New York: David MacKay. | 39, 45, 89, 224 |
| Herxheimer A (2003), Relationship between the pharmaceutical industry and patients' organisations. <i>BMJ</i> , Vol. 326, pp. 1208-1210. | 17 |
| Hillman A L (1982), Declining Industries and Political-Support Protectionist Motives. <i>American Economic Review</i> , Vol. 72 (5), pp. 1180-1187. | 48 |
| Hojnacki M (1997), Interest Groups Decision to Join Alliances or Work Alone. <i>American Journal of Political Science</i> , Vol. 41, pp.61-87. | 52, 140, 253 |
| Holmer AF (2002), In the Company of Heroes, PhRMA Meeting, March 2002 < http://phrma.org/whoweare/annualmeetings/22.03.2002.501.cfm > | 67, 68, 73, 78 |

| | |
|--|---|
| Holmer AF (2004), PhRMA's 2004 Annual Meeting, <www.phrma.org/publications/admin/02.04.2004> | 67, 68, 76 |
| Howell K (2000), <i>Discovering the limits of European Integration: applying grounded theory</i> . New York: Nova Science Publishers. | 26, 94, 136, 154 |
| Howell K (2004), <i>Europeanization. European Integration and Financial Services</i> . Hampshire: Palgrave Mc Millan | 13, 14, 43, 44, 51, 89, 99, 100, 101, 138, 140, 226 |
| Hudson I (2002), Sabotage versus Public Choice: Sports as a Case Study for Interest Group Theory. <i>Journal of Economic Issues</i> , Vol. 36 (4), pp.1079-1096. | 43 |
| Hula K (1999), <i>Lobbying together: Interest Groups Coalitions in Legislative Politics</i> . Washington DC: Georgetown University Press. | 52, 140, 253 |
| Hussey J and Hussey R (1997), <i>Business Research</i> . Hampshire: MacMillan Press. | 97, 98, 103, 104 |
| Hutchinson S A (1988), <i>Education and Grounded Theory, Qualitative Research in Education: Focus and Methods</i> . New York: The Falmer Press. | 112 |
| IMS November 2005, <i>Pharmaceutical Market in Argentina</i> | 124 |
| Jobst A (2002), Foreign Lobbying in the U.S. - A Latin American Perspective. <i>European Trade Group Study Working Paper</i> , pp. 1-57. | 11, 12 |
| Johnson P M (2005), A glossary of Political Economy Terms, Department of Political Science, Auburn University <www.auburn.edu/~johnspm, 14/06/06> | 28 |
| Jordan A G, Richardson J J (1987), <i>Government and Pressure Groups in Britain</i> . Oxford: Oxford Clarendon Press. | 28, 31, 37, 40, 41, 42, 54, 68, 226 |
| Jordan G (1993), The Pluralism of Pluralism: An Anti-Theory? In <i>Pressure Groups</i> , Richardson J J. Oxford: Oxford University Press | 29, 30, 31, 32, 33, 34, 37, 39 |
| Kahneman D & Tversky A (1974), Judgment under uncertainty: <i>Heuristics and Biases</i> . <i>Science</i> , Vol. 185, pp.1124-1131 | 56 |
| Kalnes O (2001), Rationality in the development of the political sciences: the case of neo-corporatism, <i>Working paper Lillehammer College</i> (2001), 1-34. | 39 |
| Kavanagh D and Jones B (1991), <i>Pressure Groups</i> . In <i>Politics UK</i> , Jones B et al. London: Phillip Alan. | 28, 40 |
| Kelly U A (1997), <i>Schooling desire: Literacy, cultural politics, and pedagogy</i> . New York: Routledge | 95 |
| Kelso W A (1978), <i>American Democratic Theory</i> . Connecticut: Greenwood Press. | 39, 45, 89, 225, 244 |

| | |
|---|-----------------------------------|
| Kimber R (1981), Collective Action and the Fallacy of the Liberal Fallacy. <i>World Politics</i> , Vol. 33, pp. 178-196..... | 14, 41, 89 |
| Kirchner E J (1980), Interest Group Behaviour at Community Level. <i>Contemporary Perspectives on European Integration</i> . London: Aldwych. | 14, 43, 89, 138 |
| Knack S (2000), Social Capital and the Quality of Government: Evidence from the USA. <i>World Bank Policy Research Working Paper 2504</i> , pp1-32. | 189 |
| Koepl P (2001), The acceptance, relevance and dominance of lobbying the EU Commission. <i>Journal of Public Affairs</i> , Vol.1 (1), pp.69-80..... | 55 |
| Kuhn T S (1962), <i>The structure of Scientific Revolutions</i> . Chicago: University of Chicago Press..... | 97 |
| Kvavik, R B (1976), <i>Interest Groups in Norwegian Politics</i> . Oslo:Universitetforlaget..... | 39 |
| Lagerlof J (1997), Lobbying, Information, and Private and Social Welfare. <i>European Journal of Political Economy</i> , Vol. 13, pp.615-637. | 16, 60, 61, 90, 92, 138, 139, 232 |
| Latham E (1952), <i>The Group Basis of Politics</i> . New York: Cornell University Press..... | 28 |
| Laussel D & Le Breton M (2001), Conflict and cooperation. <i>Journal of Economic Theory</i> , Vol. 100, pp. 93-128..... | 51 |
| Lehmbruch G & Schmitter P (1982), <i>Patterns of Corporatist Policy Making</i> . London: Sage..... | 36 |
| Lehmbruch G (1977), Liberal Corporatism and Party Government. <i>Comparative Political Studies</i> .. | 35, 89, 222, 223 |
| Lehmbruch G, Schmitter P (1979), <i>Trends towards Corporatist Intermediation</i> . Beverly Hills, CA: Sage | 35 |
| Lenzer J (2001), The benefit of the Bargain: Link between drug company promo and formularies. <i>Praxis Post</i> , June 2001, pp.1-3. | 86 |
| Lindblom C E & Braybrooke D (1963), <i>A strategy of decision</i> . New York: The Free Press..... | 32, 221 |
| Lindblom C E (1965), <i>The Intelligence of Democracy: decision making through mutual adjustment</i> . New York: The Free Press..... | 32, 89 |
| Lindblom C E (1977), <i>Politics and Markets</i> . New York: Basic Books | 32, 33, 43 |
| Locke K (2001), <i>Grounded Theory in Management Research</i> . Thousand Oaks: Sage..... | 217 |
| Locke L F, Spirduso WW and Silverman SJ (1987), <i>Proposals that work: A guide for planning dissertations and grant proposals</i> . 2 nd Edition, Thousand Oaks: Sage. | 129 |

| | |
|---|-----------------------------------|
| Lohmann S (1993), A signalling model of Informative and Manipulative Political Action. <i>American Political Science Review</i> , Vol. 87 (2), pp.319-333. | 16, 58, 61, 90, 92, 138, 139, 231 |
| Lohmann S (1995a), Information, Access and Contributions: A signalling Model of Lobbying. <i>Public Choice</i> , Vol. 85, pp. 518-530. | 16, 60, 61, 90, 92, 232 |
| Lohmann S (1995b) A Signalling Model of Competitive Political Pressures. <i>Economics and Politics</i> , Vol 7 (3), pp. 181-206. | 59 |
| Lord MD (2000), Constituency-based Lobbying as Corporate Political Strategy: Testing an Agency Theory Perspective. <i>Business and Politics</i> , Vol. 2, No. 3, 2000, pp. 289-308. | 12 |
| Maggi G and Rodriguez Clare A (2000), Import Penetration and the Politics of Trade Protection. <i>Journal of International Economics</i> , Vol. 51 (2), pp. 287-304. | 15, 51, 52, 53, 138, 139, 140 |
| Maloney W & Jordan G (1997), <i>The Protest Business? Mobilizing Campaign Groups</i> . Manchester: Manchester University Press. | 14, 40, 41, 89, 225 |
| Manning J and Fauber J (2001), Drug Makers depend on lobbying to protect patents. <i>Journal Sentinel Online</i> < http://www.jsonline.com:80/news/state/apr01/scriptsid02020101a.asp , 22/03/02>..... | 75, 79 |
| Martin R (1983), Pluralism and the New Corporatism. <i>Political Studies</i> , Vol. 31, pp. 86-103. | 36, 39, 89 |
| Mazey S P & Richardson J J (1993), Interest Groups in the European Community. In <i>Pressure Groups</i> , Richardson J J. Oxford: Oxford University Press. | 13 |
| Meliss N (2006), Analysis: Kallas initiative about lobbying in Brussels. EurActiv, < www.euractiv.com , 9/04/06> | 13 |
| Merleau-Ponty M (1962), <i>Phenomenology of Perception</i> . New York: Humanities Press. | 104 |
| Merriam-Webster Dictionary Online(2002). | 12 |
| Miles M B and Huberman A M (1994), <i>Qualitative Data Analysis</i> . London: Sage..... | 6, 111 |
| Mitra D (1999), Endogenous Lobby Formation and Endogenous Protection: A long-run Model of Trade Policy Determination. <i>American Economic Review</i> , Vol. 89 (5), pp.1116-1143. . | 51, 54, 61, 90, 92, 237 |
| Moe T (1980), <i>The Organization of Interests</i> . Chicago: Chicago University Press..... | 14, 42, 89, 138 |
| Molina O & Rhodes M (2002), Corporatism: The Past, Present and Future of a Concept, <i>Ann. Rev. Polit. Sciences</i> , Vol. 5, pp. 305-331 | 34, 36, 38 |
| Moloney K (1996), <i>Lobbyists for hire</i> . Hants: Dartmouth Publishing Company..... | 5, 30, 32, 44, 70 |

| | |
|---|---|
| Moloney K and Jordan G (1996), Why Companies Hire Lobbyists. <i>The Service Industries Journal</i> , Vol. 16 (2), pp.242-258. | 12, 14, 43, 89, 195, 226 |
| Motheral B et al (2000), The Effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns. <i>Journal Managed Care Pharmacy</i> 6 (4), pp. 293-297. | 82, 91 |
| Natsan M (1973), <i>Edmund Husserl: Philosophy of Infinite Tasks</i> . Illinois: Northwestern University Press. | 103 |
| National Institute for Health Care Management (USA), " Prescription Drugs and Intellectual Property Protection.", August 2000. | 74 |
| National Institute for Health Care Management (USA). Prescription Drug Expenditures in 2001: Another year of escalating costs, April 2002. | 76 |
| Neske F (1997), <i>PR-Management</i> . Vienna: Orac Verlag. | 16, 55 |
| Olson M (1965), <i>The logic of collective action</i> . In Pressure Groups, J. Richardson, Oxford University Press. | 14, 34, 40, 41, 42, 48, 54, 89, 138, 140, 209, 225, 226 |
| Oxford English Dictionary Online (2002), Second Edition, 1989, | 11 |
| Pecorino P (1997), Exogenous Tariff Changes with an Endogenous Lobby. <i>Public Choice</i> , Vol. 92, pp. 91-108. | 48 |
| Peltzman S (1976), Toward a more General Theory of Regulation. <i>Journal of Law and Economics</i> , Vol. 19 (2), pp.211-240. | 48, 228 |
| Pilnick A, Dingwall R and Starkey K (2001), Disease Management: definitions, difficulties and future directions. <i>Bulletin of the WHO</i> (2001), 79, pp. 755-763. | 80, 81, 82, 83, 91, 139 |
| Polsby N (1971), <i>Community Power and Political Theory</i> . New Haven: Yale University Press. | 31, 89 |
| Potters J and van Winden F (1992), Lobbying and asymmetric information. <i>Public Choice</i> , Vol. 74, 269-292. | 16, 56, 90, 138, 139, 230, 247 |
| Public Citizen (2001), <www.citizen.org/30 years, 03/04/02> | 11, 42, 90, 91 |
| Puig Junoy J (2005), <i>Política, Economía y Gestión de Medicamentos</i> . Santa Fe: Publicaciones Colegio de Farmacéuticos de Santa Fe. | 65 |
| Quenell P (2003), Getting a word in edgeways? Patient group participation in the appraisal process of NICE. <i>Clinical Governance: An International Journal</i> , Vol. 8, No. 1, pp. 39-45. | 18 |

| | |
|--|---------------------------------------|
| Quenell P (2001), Getting their say, or getting their way? Has participation strengthened the patient in the National Institute for Clinical Excellence? <i>Journal of Management in Medicine</i> , Vol. 15, No. 3, pp. 202-219..... | 17 |
| R Bengoa, Recent Tendencies and reforms of the Health Systems. Internal markets with and without competition and integrated health systems. <i>Anales de la Universidad de Navarra</i> , february 1998, pp.44-52..... | 81 |
| Rama M and Tabellini G (1998), Lobbying by capital and labour over trade and labour market policies. <i>European Economic Review</i> , Vol. 42, pp. 1295-1316..... | 15, 51, 53, 61, 90, 92, 140, 234, 262 |
| Rasmusen E (1993), Lobbying when the decision-maker can acquire independent information. <i>Public Choice</i> , Vol. 77, pp. 899-913. | 58 |
| Redwood H (1997), Pharmacopolitics 2000: cost containment vs. quality. <i>Scrip Magazine</i> February 1997, pp. 50-52..... | 66, 82 |
| Redwood H (2002), Whatever happened to industrial policy?. <i>Scrip Magazine</i> October 2002, pp.7-9..... | 66, 80 |
| Richardson JJ (1993), <i>Pressure Groups</i> . Oxford: Oxford University Press..... | 43, 227 |
| Rodrik D, Grossman G & Norman V (1995), Getting Interventions Right: How South Korea and Taiwan Grew Rich. <i>Economic Policy</i> , Vol. 10 (20), pp.53-107..... | 50 |
| Rogers W A (2003), Ethical issues in public health: a qualitative study of public health practice in Scotland. <i>Journal of Epidemiology Community Health</i> , Vol. 58, pp. 446-450. | 18 |
| Rokkan S (1966) Norway: Numerical Democracy and Corporate Pluralism. In <i>Political opposition in Western democracies</i> , Dahl R A. New Haven: Yale University Press. | 39 |
| Romar Consulting Associates, (2002)< www.romarconsulting.com/images/cdbrochure.pdf , 3/03/02> | 84 |
| Rosales J (2006), Cuando el lobby está bajo sospecha. <i>La Nación</i> , 2 July 2006, p.8. | 13 |
| Rötheli T F (2005), Applied Welfare Economics with Bounded Rationality: Public Policies Toward Remote Sensing. <i>International Advances in Economic Research</i> , Vol. 11, pp. 39-47..... | 56 |
| Rothenberg L (1992), <i>Linking Citizens to Government: Interest Group Politics at Common Cause</i> . Cambridge: Cambridge University Press. | 41, 89 |
| Rubin H J and Rubin I S (1995), <i>Qualitative Interviewing: The Art of Hearing Data</i> . Thousand Oaks: Sage | 109 |
| Salisbury R (1969), An Exchange Theory of Interest Groups. <i>Midwest Journal of Political Science</i> , Vol. 13 (1), pp.1-32. | 14, 34, 40, 41, 42, 89, 226 |

| | |
|--|------------------------------------|
| Salisbury R (1984), Interest Representation: The dominance of Institutions. <i>American Political Science Review</i> , Vol. 78 (1), pp.64-78..... | 13, 14, 42, 89, 125, 138, 225, 226 |
| Saltman R B (2002), The Western Experience with Health Care Reform. <i>European Observatory on Health Systems and Policies</i> <www.observatory.dk, 21/06/06> | 64 |
| Sargent T J (1993), <i>Bounded Rationality in Macroeconomics</i> . Oxford: Oxford University Press. | 56 |
| Saville-Troike M (1982), <i>The Ethnography of Communication: An Introduction</i> . Massachusetts: Blackwell..... | 141 |
| Schattschneider E E (1960), <i>The Semi-Sovereign people: a Realist's View of Democracy in America</i> . New York: Holt, Rinehart & Winston. | 33 |
| Schmitter P C (1974), Still the century of corporatism? <i>Review of Politics</i> , No. 36. pp.85-131.... | 34, 35, 37, 38, 89, 222, 223 |
| Schmitter P C (1981), <i>Organizing interests in Western Europe: Pluralism, Corporatism and the transformation of Politics</i> . Cambridge: Cambridge University Press. | 28 |
| Scholzman K L (1984), What Accent the Heavenly Chorus? Political Equality and the American Pressure System. <i>Journal of Politics</i> , Vol. 46, pp.1006-1032..... | 43, 89 |
| Schön D (1991), <i>The Reflective Practitioner</i> . Hants: Ashgate Publishing Ltd | 152 |
| Sent E M (2005), Simplifying Herbert Simon. <i>History of Political Economy</i> , Vol.37 (2), pp.227-232. ... | 55, 56 |
| Shonfield A (1965), <i>Modern Capitalism: the Changing Balance of Public and Private Power</i> . Oxford: Oxford University Press. | 34, 222 |
| Simon H A (1955), A Behavioural Model of Rational Choice. <i>Quarterly Journal of Economics</i> , Vol. 69 (1), pp. 99-118..... | 16, 55, 229, 230 |
| Simon H A (1956), Rational Choice and the Structure of the Enviroment, <i>Psychological Review</i> , Vol. 63 (2), pp. 129-138. | 55 |
| Simon H A (1972), Theories of Bounded Rationality. In <i>Decision and Organization</i> Mc Guire C B and Radner R, pp. 161-176. North-Holland:Amsterdam..... | 56 |
| Spradley J P (1980), <i>Participant observation</i> . New York: Holt, Rinehart and Winston..... | 141 |
| Stigler G (1971). The theory of Economic Regulation. <i>Bell Journal of Economic and Management Science</i> , Vol 1 (1), pp.1-21. | 47, 228 |

| | |
|--|---|
| Strauss A & Corbin J (1990), <i>Basics of Qualitative Research - Techniques and Procedures for Developing Grounded Theory</i> . 1st. Edition, Thousand Oaks: Sage. | 106, 107, 112, 114, 116, 151, 213 |
| Strauss A & Corbin J (1998), <i>Basics of Qualitative Research – Techniques and Procedures for Developing Grounded Theory</i> . 2 nd . Edition, Thousand Oaks: Sage. ... | 19, 20, 24, 94, 107, 110, 112, 113, 114, 115, 116, 117, 118, 121, 122, 152, 214 |
| Strauss A (1987), <i>Qualitative Analysis for Social Scientists</i> . Cambridge: Cambridge University Press. | 114 |
| Studin I (2002), Reframing the Pharmaceutical Manufacturer/ Health Plan Relationship in Managed Care, <i>Managed Care</i> February 2002, pp.46-54. | 82, 83, 85, 88, 91, 138, 139, 241 |
| Studin I (2004), New Horizons in Pharmaceutical Managed Care Marketing, <i>Pharmaceutical Executive</i> Vol.24 (10), pp.100-111. | 85 |
| Suranovic S (2001), The nature of Lobbying. <i>International Trade Theory and Policy Lecture Notes</i> (2001) <www.internationalecon.com/v1.0/ch105, 09/10/02> | 79 |
| Susman T (2006), Reciprocity underlies lobbying scandals. <i>The Hill</i> , 28 June 2006, www.hillnews.com. | 189 |
| Tarnas R (1993), <i>Passion of the Western Mind</i> . New York: Ballantine Books..... | 95, 96 |
| Thompson C J et al (1990), The lived meaning of free choice. <i>Journal of Consumer Research: An Interdisciplinary Quarterly</i> . Vol. 17, (3), pp.346-361. | 104 |
| Tilly C (1978), <i>From mobilization to revolution</i> , Reading: Addison-Wesley..... | 31 |
| Tobar F (2002), Volver a regular: el uso de la Farmaeconomía y los desafíos de la regulación de medicamentos. <i>Publicaciones ISalud</i> , Buenos Aires, pp. I-19. | 66 |
| Trafford V (2001), <i>An Unravelling of Research Methodology</i> . Anglia Business School Research Papers. London: Earlybrave Publications | 97, 99, 100, 101, 105, 109 |
| Traxler F (1991), Regieren die Verbände?, Ihr wirtschaftspolitischer Einfluss und dessen Effekte im internationalen und intersektoralen Vergleich. In Hartwich H H and Wewer G, <i>Regieren in der Bundesrepublik</i> . Wiesbaden: Leske und Budrich Verlag, pp. 135-150. | 38 |
| Truman D B (1951), <i>The Governmental Process: Political Interests and Public Opinion</i> . New York: Knopf..... | 30, 31, 89, 221 |
| Van Maanen J (1979), Reclaiming qualitative methods for organizational research: A preface. <i>Administrative Science Quarterly</i> , Vol.24 (4), pp.520-526 | 108 |
| Varney C A (1995), The Dangers of Health Industry Consolidation and Corporization and the Effect on Quality, Cost and Access. <i>Drug Industry Panel, Federal Trade Commision</i> , May 1995..... | 81 |

- Vasallo C, MB Sellanes (2002), *Demanda y Acceso a los Medicamentos: El caso Antrax-Cipro como disparador del debate internacional*. Buenos Aires: Observatorio de Salud, Medicamentos y Sociedad. 73
- Vincent R (2003), A Comparative Perspective of the Health Systems available in the Developed Nations, *Working paper CAEMe*, Buenos Aires. June 2003. 17, 63, 65, 90
- Walker J (1983), The Origins and Maintenance of Interest Groups in America. *American Political Science Review*, Vol. 77, pp.390-406. 14, 42, 71, 89, 226
- Walker J (1991), *Mobilizing Interest Groups in America: Patrons, Professions and Social Movements*. Michigan: University of Michigan Press. 14, 41, 89
- Wassenberg A (1982), Neo-corporatism and the quest for control: the cuckoo game. In G. Lehmbruch & P. Schmitter (Eds.), *Patterns of corporatist policy-making*, pp. 83-108, London: Sage. 38, 89, 223, 244, 245, 261
- Wessels, B (1997), Interest Groups and Political Representation in Europe. *Paper presented at Workshop ECPR*, Bern, February 27- March 4, 1997, pp.1-25. 37
- Wexler C, Steiner D, Shaffer M and Rabin S (2001), Prescription For Power: How Brand Name Drug Companies prevailed over consumers in Washington. *Common Cause Publications*, Washington DC, July 2001 11, 68, 69, 73, 74, 75, 77, 78
- Williamson P J (1985), *Varieties of corporatism: Theory and Practice*. Cambridge: Cambridge University Press. 37
- Wilson J Q (1973), *Political Organizations*. New York: Basic Books. 31
- Woll C (2006), Lobbying in the European Union: from sui generis to a comparative perspective. *Journal of European Public Policy*, Vol.13 (3), pp.456-469.14, 15, 43, 44, 45, 89, 138, 227, 245, 247, 261
- Yin R K (1994), *Case Study Research: Design and Methods*. Thousand Oaks: Sage 20, 105
- Young B, Surrusco M (2001), The other Drug War: Big Pharma's 625 Washington Lobbyists. *Public Citizen Congress Watch Publications*, Washington DC, July 2001, pp.1-40. 68, 71, 76

APPENDIX 1

1st SET OF CATEGORIES

| Sub-categories | Concepts | Sub- concepts/processes | Labels |
|------------------|---|---|---|
| Health System | Care Government/ officials/ pharmaceutical companies/ pharmacopolitics manager/ chamber | Hierarchical structure of decision/ formularies/ patient | Delegated in intermediate/lack of control/subsidies inexistence/ commercial interest / government/ state/ officials/ hierarchical structure of decision/ formularies/ ideology/ formularies/ patient role/ fragmented/ HMOs/ companies/ pharmacopolitics manager/ chamber |
| Market | Sales methodology/ sales objectives/ | Pathology programs/ direct purchases/ catastrophic diseases/ formulary positions | Market/ sales methodology/ pathology programs/ direct purchase of products through HMOs/ catastrophic diseases/ access/ sales/ specific/ stable/ predictable/ economic context/complexity/ formulary positions/ competitors/ attention of officials/ |
| Competence | Inclusion formularies/ officials research/ preparation dossier | Trust/ expertise/ scientific support | Inclusion formularies/ expertise/ knowledge/ scientific support/ market research/ formulary research/ dossier/ disease management/ preparation/ HMOs research/ habits/ trust/ |

| Product Value | Quality/ broadly use | Essential/ Essential | Social commercialization value/ scientific value | Quality/ broad use/ narrow use/ characteristics/ social value/ scientific value/ economic value/ specialization/ arbitrary value |
|-----------------------------|---|-------------------------|--|---|
| Interests representation | Motivations/ Objectives/ | | Increase sales/ introduction of products/ maintain market share/ simplify negotiations | Companies objectives/ increase sales prices/introduction of products/ influence decisions/ maintain market share/ simplify negotiations/ institutional level/ institution- personal/ personal-personal/ welfare/ interests/ official demands/ |
| National Policy | Legislation/ regulation/ policies | market health | High-rank reference generics | Legislation/ modification of policies/changeable / flexible/ influence on policies/ moral/ high-rank officials/ market regulation/ reference prices/ generics/ judiciary system/ health policies/ |
| Demand | Transmission information/ contribution payments | of | party pathology programs/ cost reduction/ ethics | Party financing/ pathology programs/ emergency situations/ personal contribution payments/ personal problems solving/ scientific interest/ economic convenience/ cost reduction/ ethics/ transmission of information |

| | | | |
|---|--|---|---|
| Interest Groups | HMOs, pharmaceutical companies/ pharmaceutical industry/ chamber | Pharmacopolitics managers | Participants /HMOs /companies/ pharmacopolitics managers/ chambers/ interest representation/ bureaucracy/ enhance the decision power/ pharmaceutical industry/ corporate feeling/ chamber |
| Negotiation | Strategy/ agreement/ relationships | Anticipation/ observation/ negotiation/ results | Strategy/ anticipation/ attention/ proactive/ offer possibilities/ observation/ participation in state programs/ decision/ study of the situation/ obtain information/ personal relationships/ degree of contact/ interest agreement/ ranking in the relationship/ close relationships/ essential/ relationship environment/ negotiation parties/ decision power/ lobbying/ offer/ negotiation/ results |
| International/ National Pressures | American Embassy/ Chambers/ Congress | Patent legislation/ | American embassy/ congress/ patent/ PHRMA/ national companies/ PMO/ generic companies/ |

2nd SET OF CATEGORIES

| Sub-categories | Concepts | Sub-concepts/processes | Labels |
|------------------------------------|--|--|---|
| Health System | Care pharmacopolitics manager/ officials/ external lobbyists chamber/ | Government/ HMOs/ pharmaceutical companies/ | Delegated in intermediate/lack of control/subsidies inexistence/ commercial interest / government/ state/ officials/ formularies/ ideology/ patient role/ fragmentation/ HMOs/ pharmacopolitics manager/ chamber/ interaction/ external lobbyists/ pharmaceutical companies |
| Hierarchical structure of decision | Change of target for lobbying/ official empowerment | Physician-official role/ high ranking officials/ formularies | Change of decision power/ officials empowerment/ physician role/ target/ high-ranking officials/ opinion leaders/ niche product/ formulary positions/ government/ formularies |
| Market | Sales methods/ | Pathology programs/ direct purchases/ | Market/ sales methods/ pathology programs/ direct purchase of products through HMOs/ access/ sales/ specific/ stable/ predictable/ economic context/complexity/ competitors/ |
| Objetives | Inclusion formularies/ increase profit and sales/ influence decisions/ simplify | Strategic products/ maintain formulary positions/ disease | companies objectives/ increase sales /introduction of products/ influence decisions/ maintain market share/ simplify negotiations /inclusion formularies/ disease management programs/ strategic products/ direct sales to |

| | negotiations/ market share | management programs | HMO/ increase prices/ increase profit/ maintain formulary positions |
|------------------------|---|---|---|
| Product Value | Quality/ broadly use/scientific support | Social economic scientific value | Quality/ broad use/ narrow use/ essential/ scientific characteristics/ social value/ economic value/ scientific value/ economic value/ specialization/ high technology |
| Strategy | Officials research/ preparation of dossier/ lobbying strategy/ | Scientific support/ formulary evaluation | expertise/ knowledge/ scientific support/ market research/ formulary evaluation/ dossier/ HMOs research/ habits/ trust/ preparation dossier / lobbying strategy/ |
| Building relationships | Building negotiation enviroment | Close informal long-term personal relationships/ high-ranking officials | Trust/ close relationships/ high-ranking officials/ essential/ personal/ informal/ stable/ negotiation environment/ influence officials/ hospitality/ long-term/ degree of contact/ |
| Interests agreement | HMO rebates/ official contributions/ scientific evidence | HMO costs/ product prices/ official demands | HMO rebates/ official contributions/ scientific evidence/ HMO costs/ product prices/ essential/ affiliates welfare/ special needs/ official demands/ |
| National Policy | Legislation/ regulation/ health | reference prices/ generics | Legislation/ modification of policies/changeable / flexible/ influence on policies/ moral/ market regulation/ reference |

| | polices | | | prices/ generics/ judiciary system/ health policies/ |
|--------------------------------|---|---|--|--|
| Needs of officials | Transmission of information/ contribution payments | Party financing/ pathology programs/ cost reduction/ ethics | | Party financing/ pathology programs/ emergency situations/ personal contribution payments/ personal problems solving/ scientific interest/ economic convenience/ cost reduction/ ethics/ transmission of information |
| Interest Groups/ | pharmaceutical companies/ pharmaceutical industry/ chamber/ lobbying actors | Pharmacopolitics managers/ free-lance lobbyists/ American Embassy | | Participants / pharmaceutical companies/ pharmacopolitics managers/ chambers/ interest representation/ bureaucracy/ enhance the decision power/ pharmaceutical industry/ corporate feeling/ chamber/ free-lance lobbyists/ American Embassy/ lobbying actors |
| Negotiation | Negotiation process | observation/ contribution offer/ negotiation/ evaluation of proposal/ results | | attention/ proactive/ contribution offer/ observation/ decision/ study of the situation/ obtain information/ negotiation parties/ decision power/ lobbying/ offer/ negotiation/ results/ evaluation of proposal |
| Contribution and communication | Transmission of information/ contribution payments | Information costs/ pharmaceutical studies/ rebates | | Scientific evidence/ high-technology/ pharmaeconomic studies/ information costs/ registration process/ dossier/ clinical evidence/ rebates/ contribution payments/ |

| | | | | |
|---|---|--|--|--|
| | | | | information transmission/ other contributions/ |
| International/ National Pressures | American Chambers/ Congress | Embassy/ Patent legislation/ | American embassy/ congress/ patent/ PHRMA/ national companies/ PMO/ generic companies/ | |
| Cooperative lobbying | Chambers/ Group of companies/ Coalitions/ Free-ride | Large government/ lobbying clout | Large HMOs/ corporate feeling/ government/ individual lobbying/ group of companies/ punishments/ establishment/ controversy/ national companies/ free-ride/ exclusion/ interest representation/ stronger position | |

FINAL SET OF CATEGORIES

| Sub-categories | Concepts | Sub-concepts/processes | Labels |
|---------------------|---|--|--|
| Target for lobbying | Officials/ Change of target for lobbying/ | Government/ HMOs/ high ranking officials/ Physician-official role/ formularies | government/ state/ officials/ formularies/ patient role/ HMOs/ interaction/ change of decision power/ officials empowerment/ physician role/ target/ high-ranking officials/ opinion leaders/ niche product/ government/ |
| Motivations | Inclusion formularies/ increase profit and sales/ influence decisions/ simplify negotiations/ maintain market share | Strategic products/ maintain formulary positions/ disease management programs | companies objectives/ increase sales /introduction of products/ influence decisions/ maintain market share/ simplify negotiations /inclusion formularies/ disease management programs/ strategic products/ direct sales to HMO/ increase prices/ increase profit/ maintain formulary positions |
| Participants | Pharmacopolitics Managers/Public officials/ HMOs officials/ pharmaceutical companies/ | Active participants/ Passive participants/ Occasional participants | Participants / pharmaceutical companies/ pharmacopolitics managers/ chambers/ interest representation/ bureaucracy/ / pharmaceutical industry/ chamber/ free-lance lobbyists/ American Embassy/ lobbying actors/ degree of participation |

| | | | |
|---------|--|------------------------------|--|
| | government/ Chamber American Free-lance pharmaceutical industry/ chamber/ lobbying actors | | |
| Product | Quality/ broadly used/scientific support/ social value/ economic value/ scientific value | High-technology/ efficacy | Quality/ broadly used/ narrow use/ essential/ scientific characteristics/ social value/ economic value/ scientific value/ economic value/ specialization/ high technology/ efficacy |

| | | | |
|-------------------------|---|--|--|
| Building trust | Building relationships/ negotiation enviroment/ | Close informal long- term personal high- relationships/ high- ranking officials | Trust/ close relationships/ high-ranking officials/ essential/ personal/ informal/ stable/ negotiation environment/ influence officials/ hospitality/ long-term/ degree of contact/ |
| Cooperative lobbying | Chambers/ Group of companies/ Coalitions/ Free-ride | Large HMOs/ government/ stronger lobbying clout | Large HMOs/ corporative feeling/ government/ individual lobbying/ group of companies/ punishments/ establishment/ controversy/ national companies/ free-ride/ exclusion/ interest representation/ stronger position |
| | ethics | | |

| | | | | |
|----------|---|--|---|--|
| Strategy | <p>Preliminary obtain preparation/ negotiation/ results</p> | <p>Officials preparation of dossier/ lobbying official contributions/ scientific evidence/ transmission of information/ contribution payments/ negotiation process</p> | <p>knowledge/ scientific support/ dossier/ HMOs research/ habits/ trust/ lobbying strategy/ HMO rebates/ scientific evidence/ HMO costs/ affiliates welfare/ special needs/ legislation/ modification of policies/ influence on policies/ moral/ situations/ personal contribution problems solving/ scientific interest/ cost reduction/ ethics/ representation/ proactive/ decision/ study of the situation/ negotiation parties/ negotiation/ results/ pharmaeconomic studies/ process/ dossier/ clinical evidence/ contributions/</p> | <p>formulary evaluation/ preparation dossier / official contributions/ essential/ official demands/ changeable / flexible/ emergency payments/ personal convenience/ interest observation/ information/ offer/ proposal/ costs/ registration rebates/ other contributions/</p> |
|----------|---|--|---|--|

APPENDIX 2

Summary of the Research

Pharmaceutical Industry lobbying in Argentina: A study of Pharmacopolitics

Pharmacopolitics activities have begun recently in Argentina as a response to changes in the Health System regarding the regulation of HMOs and the creation of HMO's formularies. Due to this changes, Pharmaceutical Multinational Companies have decided to create the job of Pharmacopolitics Manager, who is in charge of securing formulary positions and managing the relationship between the company and the Government.

The aim of the research project is to investigate two main topics regarding Pharmacopolitics:

- The relationship between the Pharmaceutical Industry and the Government and how the Industry influences legislation and Government decisions.
- The relationship between the Pharmaceutical Industry and the HMOs and the importance for the Industry to secure Formulary positions.

Mi name is Javier de Renteria and I am working for Alcon Laboratories as a Managed Care Manager. I am a doctorate candidate at Anglia Polytechnic University, Danbury Park, Danbury, Chelmsford CM3 4AT.

I would like to invite you to participate in the research project. The participation procedure will be to have an interview with you. It will take between 45 to 90 minutes. The information that you give me in the interview will be used in my research project and eventually in the Thesis. I am funding myself the research. My mobile phone number is 15-5008 3961 and my E-mail address is javierderenteria@fibertel.com.ar.

You have been invited to take part due to your deep knowledge and broad experience in the research subject: Pharmapolitics.

You may feel free to refuse to take part and you can withdraw at any time just by sending me by registered post the copy of the Withdrawal Form to the following address:

Mr. Javier de Renteria
Club Newman
Ruta 9 Km. 39,5
1621 Benavidez
Buenos Aires

If you agree to take part, you will be interviewed by myself and the information will be transcribed for further analysis. A code number will be assigned to the transcription for anonymity reasons. The transcriptions will be kept in the researcher's home in a closed box. No e-mail will be sent with the transcript of the interviews. The information of the interview will be analysed only by the researcher.

There are no foreseeable risks involved. Confidentiality will be granted and the researcher will put special emphasis that no response would be construed as representing the particular respondent.

Agreement to participate in this research will not compromise your legal rights in case something goes wrong.

There are no economic benefits from taking part in the research project. Your participation will contribute to expand the general knowledge in the research subject.

**YOU WILL BE GIVEN A COPY OF THIS TO KEEP
TOGETHER WITH A COPY OF YOUR CONSENT FORM**

Participant Consent Form

Informed consent - Pharmaceutical Industry lobbying in Argentina: A study of Pharmacopolitics

NAME OF PARTICIPANT:

Investigator and contact details:

Mr. Javier de Renteria
Club Newman
Ruta 9 Km. 39,5
1621 Benavidez
Buenos Aires

Mobile phone : 15-50083961

E-mail : javierderenteria@fibertel.com.ar

1. I agree to take part in the above research. I have read the Participant Information Sheet which is attached to this form. I understand what my role will be in this research, and all my questions have been answered to my satisfaction.
2. I understand that I am free to withdraw from the research at any time, for any reason and without prejudice.
3. I have been informed that the confidentiality of the information I provide will be safeguarded.
4. I am free to ask any questions at any time before and during the study.
5. I have been provided with a copy of this form and the Participant Information Sheet.

***Data Protection: I agree to the University¹ processing personal data which I have supplied.
I agree to the processing of such data for any purposes connected with the Research
Project as outlined to me****

Name of participant (print).....Signed.....Date.....

Name of witness (print).....Signed.....Date.....

YOU WILL BE GIVEN A COPY OF THIS FORM TO KEEP

¹ "The University" includes APU and its partner colleges

If you wish to withdraw from the research, please complete the form below and return to the main investigator named above.

Title of Project: Pharmaceutical Industry lobbying in Argentina: A study of Pharmacopolitics

I WISH TO WITHDRAW FROM THIS STUDY

Signed: _____

Date: _____

APPENDIX 3

Prospective view of the Health System in Argentina

Author: Javier de Renteria

June 2002

Prospective view of the Health System in Argentina

Purpose: To evaluate the different views of the political players and the Pharmaceutical Industry on the changes that will happen in the next 5 years in the Health System in Argentina.

Methodology: The methodology was based in open Interviews done to key people in the two main political parties and the Pharmaceutical Industry. For the Peronist party, now in the Government, the two interviews were done to Lic. Federico Tobar and Dr. Nestor Vazquez. Lic. Federico Tobar is the Chief Advisor to the Minister of Health and Director of Research of Isalud Foundation (the most important think-tank in Health Issues in Argentina). He has participated in more than 30 projects in the area of Health Management and Policy sponsored by the Kellogs Foundation, the Government of Brasil, the Panamerican Health Organization, the International Development Research Centre and the United Nations. He has published more than 60 articles and is co-author of 8 books regarding Health Policy. Dr. Nestor Vazquez is the General Manager of the Health Services Superintendence, the body of control of the Health System. Previously he has been advisor to the Health Committee of the Deputies Chamber (2000 –2001), advisor to the Health Committee of the Senators Chamber in Buenos Aires Province (2000) and he has been the author of the law which regulates the PMO (Compulsory Medical Care) and he collaborated with the formulation of the AIDS and Addictions Law. Additionally he has published numerous articles and he is co-author in several books on Health issues.

For the opposition, the Radical Party, the interviews were done to Dr. Carlos Vasallo and Dr. Carlos Neri. Dr. Carlos Vasallo is the President of the Argentine Association of Health Economics (2000-2002), Director of the "Observatorio de Salud", Research Institute of the Chamber of Pharmacies, Professor of Health Economics in Isalud Foundation and in Instituto Lazarte (National University of Rosario). He has also published several articles in national and international journals and he is co-author in the book "Demand and access to medicines". Dr. Aldo Neri is a National Deputy and member of the Health Issues Committee of the Deputies Chamber. He was appointed

as Minister of Health from Dec- 1983 to Jun-1986 when he was transferred to another position in the Government. He was Deputy for the Radical Party between Dec- 1987 and Dec-1991. Afterwards he was appointed as Secretary of Health for the City of Buenos Aires (May-2001 to Nov-2001). He has also received the award: "Health for everyone" (April 1988) from the WHO (World Health Organization). He has published more than 100 articles regarding Health, Society and Politics and he is the author of 2 books on Health and Politics.

For the Pharmaceutical Industry, the interviews were done to Mr. Ernesto Felicio, President of the Multinational Pharmaceutical Companies Chamber and Mr. Victor Quiñones, Manager for International Relations from the Multinational Pharmaceutical Companies Chamber. Mr. Ernesto Felicio has been working previously as General Manager for Bristol Myers Argentina and he has more than 20 years experience in the Multinational Pharmaceutical Industry in different positions in Argentina and in the USA. Mr. Victor Quiñones is the Head Researcher for the Multinational Pharmaceutical Companies Chamber and is also the Coordinator of economic studies of the Latin-American Federation of the Pharmaceutical Industry.

The main issues that were surveyed were:

- ⇒ Role of the Government in the restructuring of the Health System
- ⇒ Health Management Organisations (HMOs)

Trade Unions

Provinces

PAMI (for the elderly people)

Private

- ⇒ New role and restructuring of the Public Hospitals
- ⇒ Product Formularies within the HMO's (Vademecums)

Introduction

There are three characteristics that should be pointed out of the Argentina Health System. The first one is that was not centrally planned by the Government and that it developed itself according to the political and economic circumstances of the different periods. The second one is that it is fragmented and that this fragmentation led to an overcapacity of physicians, Clinics and Hospitals. And the third one is that, according to Dr. C. Vasallo is more similar to the American System than the European one, being Health considered a private good which depending in the purchasing power the individual has, could be obtained or not. So that there has been a problem of equality in the access to Health Care related to the inequality in the distribution of income.

The role of the Government in this process was always erratic; sometimes being quite active and other times leaving the players in the System to their own fate and their own rules. But it should be pointed out that the State was always a big financier of the whole System and there are some Health Management Organisations (HMOs), which cannot survive without being funded by the state.

How did the process of building up the Health System begin? The process began last century around 1930's when a big immigration flow came from Europe, mainly from Spain and Italy. Big Hospitals were built by the State and Health was provided at no cost for all the inhabitants. The more affluent could afford private care, paid by themselves in some private Clinics. There was one Trade Union, Ferroviarios (Train workers) which began providing some Health Care at the beginning of the Century but it was an exception.

Between the 40s and the 50s, the Trade Unions flourished under the First Presidency of Peron. The employees of some State Companies created the first important Trade Unions HMOs. Peron supported these types of organisations and the workers began to have right under the laws and services (Health Care, Tourism, etc.) from the Trade Unions. Regulation was issued so that the employees and employers had to contribute

with part of their income to finance the Trade Union HMOs and this modality is still in practice.

Each Trade Union had to build an infrastructure to provide Health Care to their affiliates and sub-contracted Private Clinics and physicians. The affiliate could choose between those physicians and Clinics sub-contracted by the HMO, so that there is no free election. Some big Trade Unions built their own Hospitals and Clinics, but a lot of them had to be closed as people move to new trades. But in terms of numbers of affiliates, these HMOs account for only 25% of the whole population. The other 75% was not covered. Nevertheless it was the first step to the introduction of some type of Health Care, together with rights for the workers.

In 1970, Carlos Onganía, a de-facto President from the Military Junta issued the law 18610, which introduces and generalizes the HMO System for all the people who are working for a public or private company. HMO's should be created according to trade and in a few years, from 1970 to 1975 more than 60% of population was covered. The Armed Forces and the Provinces were also included.

The Provinces had a big number of employees and they had to build their own HMOs. The approach they took was similar to the one of the Trade Unions, but they did not build Hospitals but they subcontract to private providers in the Province. From these HMOs the employees still contribute with part of their salaries but the other rest was financed directly by the Province. The Armed Forces, especially within the de-facto governments, used to build big structures and big Hospitals with state-of-the-art technology, which sometimes was better than what could be found in Private Clinics. The way that they were financed was similar to that of the Provinces.

In the 70's there was also a milestone, which changed the whole Health System, and it was the creation of PAMI (HMO for pensioners). The different HMOs had the burden of the elderly, being this part of the population, the one with higher costs. Due to this fact, they were having financial problems. In order to solve this issue, the

Minister of Health and Social Security at that moment, Dr. Manrique, decided to create PAMI as an HMO which was going to be responsible to provide Health Care to the pensioners. As soon as the people retired, they switched from their HMO to PAMI. This creation changed the history and it has been always a political issue because of the importance in votes (4.000.000 people) and also because an important part of the budget of the Government is devoted to PAMI. It was created as a separate organism, to give it independence from the Ministry of Health. Not even the Health Services Superintendence, that is the organization that controls all the Health System, had an influence in PAMI.

By the end of the 70's, 85 % of population was included in a HMO, either from the Trade Union, Armed Forces, PAMI or Provinces. The rest of the population were independent as professionals, etc. or they got Health Care in the State Hospital.

In the 80's, new Private HMOs were created aimed at the Upper Class. The Upper Class used to pay themselves for Health Care not having any kind of Health Insurance. That proved to be too costly and some new players enter the market targeting two different kind of customers: middle managers and top managers in the companies which also devote part of their salaries to the Trade Union HMOs but now they could divert that money to the Private HMOs and the other part of the Upper Class which was not in an HMO, because they used to pay themselves, and now they preferred to be covered by these organizations. Afterwards these HMOs broaden their public, including people from the Medium Class and reaching agreements with companies for the whole Pay roll. The success of this Private HMOs was that they offered a better service and quality than the other ones.

In the 90's there were two big issues that influenced the System: one was external and the other internal but both represented a change in what was happening until that moment. The first issue was AIDS. Although Argentina was a low incidence Country the Government decided to cover 100% of the treatment for all the people with AIDS. A Department was created within the Health Services Superintendence to monitor

AIDS, Transplants, Haemophilia and Special Treatments. The costs of these patients will be met by the Government but treated by the different HMOs.

The other issue, which affected mainly the patients and the Pharmaceutical Industry, was the introduction of Vademecums for the Trade Unions, Provinces and Armed Forces HMOs. What is a Vademecum? It is a list of pharmaceutical products that being prescribed by the physician have a discount in the Pharmacy. Those products that are prescribed and are not in the Vademecum should be totally paid by the patient. Those, which are prescribed and are part of the Vademecum received a discount of between 40% to 100%. Before of the introduction of Vademecums, physicians could prescribe any product and the patient got always a discount. Each HMO has its own Vademecum with different products that are included. This issue created the job of Pharmapolitics in the Industry with the objective of including the products in those Vademecums so as to achieve a competitive advantage.

After all these changes, the HMOs have been living together in the last 20 years and what it is now available is a Health System with fragmentation in the providers of Health Care (physicians, laboratories and Clinics) aimed at each of these targets but almost always with overcapacity and inefficiency. The Public Hospitals still provide Health Care to the poorer people at a minimal cost but with scarcity of drugs and material, the Trade Unions still have a considerable amount of people although their service is not that good and the provinces HMOs give Health Care to more people than their affiliates as there is no control of people and practices. The Private HMOs continue in the market but they are going through a process of consolidation to achieve economies of scale. Last but not least, the control of the Government of the Health System, from the provider side (HMOs, Clinics and physicians, is almost inexistent.

So now that Argentina and the Health System is confronted with a tremendous crisis with not enough funds to continue as it was, the question arises of how will the

System change in the next 5 years. For that purpose, it would be interesting to know the prospective view of the most important political and economic players:

the Peronist Party (now in the government)

a) the Radical Party (the opposition)

b) the Pharmaceutical Industry

Prospective View of the peronist party

The Peronist Party is now in Government after the Radical Party in December withdrew of the Government. Elections will be held next year and all the polls suggest that the Peronist Party will win so that there could be continuity with the policies that are being implemented. Referring to how the Health System will change, Lic. F. Tobar remarks that there could be four scenarios:

a) Reactivation of the economy with political will to change the Health System

b) Recession with political will to change the Health System

c) Recession without political will to change the Health System

d) Reactivation of the economy without will to change the Health System

The B scenario, Recession with political will to change the Health System, represents what it is happening now. The A scenario is possible but in the future after the recession period. There is discrepancy on how long will be the B scenario between Tobar and Vazquez. Tobar gauges a period of 6 months and Vazquez talks about at least 12 months.

The B Scenario:

According to Vazquez during the B Scenario there would be no change in the Health System; everything will continue as it is and the lack of funds in the HMOs and the

lack of funding by the Government will bring the Health System to a standstill where the different players will try to survive. An estimate of 50% of all the companies, which import Medical Material, will disappear and some Pharmaceutical Companies will leave the country. Smaller generics companies will be working actively without Legislation that protects them and there will not be any structural changes.

From the side of the HMOs, Lic. Tobar considers that they will be cutting services and there would be a migration from the Trade Union HMOs to the Private HMOs looking for better service and from the Private HMOs to the Public Hospital as unemployment grows. The main worry of the Government, according to Tobar will be how to support the Public Hospital and give them the medicines and materials they need to provide Health Care. Some international loans are aimed at this objective. As the numbers grow at the Public Hospital, the quality will decrease, as there will not be an increase of infrastructure at them. Vazquez remarks that no new equipment and technology will be introduced because of the costs and the deterioration of the old equipment will impede to provide proper Health care. Tobar comments that according to the Ministry of Health, Dr. Gines Gonzalez Garcia, the situation is similar to the one of the Soviet Union after the default in its external debt. The average life expectancy diminished by 7 years during the Soviet Union crisis and the same is expected in Argentina.

The A Scenario:

After the Scenario B, the Scenario A will come in, with a reactivation of the economy, "with less players from the supplier side and the HMOs recovering their affiliates as unemployment decreases"(Vazquez). Regarding the Health System, Tobar and Vazquez think that the "status quo" cannot be preserved. The fragmentation of the Health System leads to overcapacity and inefficiencies that resulted in more need of resources that will not be available in the future. So that according to Vazquez, there will be an integration of all the players that are equal. Some Trade Unions HMOs will merge or make Alliances with another Trade Union HMOs and the Private HMOs will go through the same process. Those HMOs with a strong leadership will attract the others and there will be fewer players. Providers of Health

Care, physicians, laboratories and Clinics will also group themselves to offer their services to these big HMOs. This process could take twelve or sixteen months. From the funding side, Tobar suggests that it is going to be a mixed System being financed by the State and by the employers and employees.

The Program to be implemented by the Peronist Party in the Scenario A will be based in the following issues:

1) National Insurance for all the people:

The aim of this insurance is to cover all the inhabitants of the Country, including those who are poor and do not have any proper Health Coverage. The percentage of population without coverage is nowadays of 50% because of the recession but in normal times, this percentage is one third of the population. This new insurance will give access to proper medicine to all the population who are out of the formal economy. Health services will be provided in the Public Hospitals and Provincial ones. Regarding the access to medicines, these people will have access to Generics bought by the State and provided to the patients in the Hospitals. International loans and resources from the Ministry of Health will be used to finance those purchases.

Regarding "Trade Union, Provincial and Private HMOs, all the funds (from employees, employers and the State) will be diverted to a fund and each HMO will receive an amount of money per month according to the characteristics of its population calculated by an actuarial risk calculation" (Tobar). Vazquez believes that those HMOs will subcontract their providers as it is been done now. The provinces HMOs will compete also in the coverage of the people without HMO and they will sell their services to the National Insurance. On the other side, Vazquez remarked, there will be competence in quality and prices from the Health Providers (Clinics, Physicians).

2) PMO (Compulsory Medical Care):

This a list of medical practices and drugs that must be covered by all HMOs, Hospitals and the State. "An emergency PMO has been introduced now in the

crisis but a revised one will be issued in the future" (Vazquez). The list of drugs, according to Vazquez will be strict at the beginning and it will become more flexible afterwards introducing new therapeutic possibilities. The introduction in this list will depend on scientific facts and not in political or lobby actions. Tobar thinks that this list of drugs must be the same for all HMOs, but Vazquez thinks that each HMO will introduce additional drugs according to the characteristics of their population. The trademarks to be included will be decided by each HMO creating their own Vademecum. Vazquez thinks that the lobby by the Pharmaceutical Industry will be still important in the future aimed at introducing own trademarks in the HMOs' Vademecums.

3) Control over the Health System:

Lic Tobar claims that the will of the Ministry of Health, Ginés Gonzalez García, is to have control of every part of the Health System, including the private HMOs. Decrees and laws might be issued so that every part of the Health System is under his authority. Now PAMI is independent, Provinces HMOs are independent, Private HMOs are independent and Trade Unions HMOs are not fully dependent. The Pharmaceutical Industry is also independent. Ginés must have a strong political support to put through this reform, as there is reluctance of all the other players.

4) Public Hospital:

Tobar believes that the Public Hospital should switch to a more managerial approach providing better results and quality. It makes no sense to introduce a National Insurance for the poor and change the current system, if the patient just gets what he is getting now. There should be resources for improving the quality of physicians, nurses, etc. and also to implement Managed Care practices like in the USA.

5) Centralized body for purchases of medicines, medical material and equipment:

According to Vazquez the objective is to buy cheaper and to be able to provide more with the same resources to all the Health System. This Centralized Body will not pay Value Added Tax so that the goods will be cheaper. Nowadays all the purchases of the Government and Hospitals are decentralized except for the AIDS products. The Central Government will be doing big tenders and supplying to Hospitals and Public Institutions through the whole country. This centralized body could also give service to other players in the market as HMOs. Tobar describes that there has been an experience in Argentina with this centralized buying between 1982 to 1986 with dreadful results. The medicines never reached the ones who needed them and a lot of this medicines expired before they could be used. There was big deal of corruption in the purchasing body. Tobar believes that this idea could only be implemented when the logistic is well done. This apparent savings that will be achieved buying centrally could be shadowed by the inefficiencies of the whole system.

6) Catastrophic diseases:

There are some diseases like AIDS, Haemophilia, Transplants, Cancer and others with a high cost for the Health Care System. The idea is "to create a National Insurance for these Catastrophic diseases" (Vazquez). Those beneficiaries with a disease above certain amount per year should be included in this insurance, loosing the coverage of their HMO. Tobar points out that small excellent HMOs, from about 10.000 to 15.000 people cannot survive when they have for example, 4 transplanted patients with a costly therapy with immunosuppressives. Those patients should be covered by the State directly and the State will sub-contract the providers of Health Care for those patients. Vazquez claims that some providers will concentrate all the business being more efficient than the others and achieving economies of scale. The diseases included will be Haemophilia, Transplants, AIDS and Cancer. The main concern for the Government will be "how to finance these diseases as the number of cases of AIDS and Cancer are growing" (Tobar).

7) Generics:

The objective of the Ministry of Health, Dr. Gines Gonzalez Garcia is to introduce the concept of Generics in the population so that more people can afford medicines. The Patent Law regarding drugs has been introduced on November 2001, so that there were a lot of copies of the original products with different trademarks. There were times that a national company has launched a product before the researcher of the drug. This freedom in the Market has led to the building of a strong National Industry, which accounts for 55% of the Pharmaceutical Market. These products with different trade- marks were not cheap and they normally have the same price as the multinational companies. Tobar states that the concept of Generics that the Ministry of Health has, is different; he thinks on cheap producers with good quality and that the people will have access to them in pharmacies. The Pharmacist will be entitled to switch products upon the request of the patient. A decree has already been issued by the Ministry of Health. There are some drawbacks to this policy that are:

- a) Vazquez remarks that this type of companies amount for a small amount of the sales of the market and they are more concentrated in the Hospital Market. They do not have the necessary Working Capital to produce in the numbers needed to increase their penetration in the Ambulatory Market. Also their distribution to pharmacies do not exist or it is concentrated in the big cities, so that the poorer who are around the country and away of civilization have no access to this type of products.
- b) The quality of this type of products is rather poor so that they do not fulfil their therapeutic effect increasing the cost for the whole system. There are no studies of bioavailability or bioequivalence between the Generic and the trademark ones. These studies should be implemented in the future according to Tobar.
- c) Another issue quoted by Lic. Tobar is that the Government is only thinking in the Policy of access to medicines but not in the policy of production and encouragement of the strong National Industry. Taking

into consideration the local industry could be positive so as to assure the quality of products and give employment to the whole sector. There is a project of law from Dr. Alessandri, that at least one step of the production should be done in the country.

8 – PAMI:

Tobar claims that PAMI will tend to be more and more expensive as the population ages. He believes that Managed Care practices, like the ones implemented with Medicare in the USA, should be introduced and PAMI should go through a restructuring and try to be more efficient. Tobar also states that PAMI should only provide Health Care to their affiliates and it should cut the services it provides like Tourism. PAMI should also be only for Pensioners, as now there are 29% of its affiliates that are not pensioners. According to Tobar, PAMI should first reactivate their services to the pensioners, rationalize itself and make itself smaller not affecting the service to the affiliates. It will continue to be centralized and in some cases where the population in one province is very small, an agreement could be achieved with the Provincial HMO. Tobar thinks that PAMI should have the same list of drugs as other HMOs but Vazquez remarks that PAMI should have its own Vademecum adapting it to the age of its affiliates as they need another type of medicines. The Vademecum of PAMI should not include milks for neonates as the National PMO does.

The other scenarios c and d are disregarded. "In case there is a recession without a will to change the Health System, there will not be any possibility to manage the situation"(Tobar). And reactivation without change will just be more of the same that we have with Menem. (1989-1998) With an Health Care expense of U\$S 700 per capita per year with a deficient quality for the patient, being the beneficiaries the Pharmaceutical Industry and the providers of Health Care (physicians, laboratories and equipment companies).

Prospective View of the Radical Party

The Radical Party is the second biggest in the Country and it has been in power two times in the last 20 years, having to quit both times before the end of the period due to an economic and social chaos. But as the opposition in the Parliament, they have a positive influence in the outcomes of the legislation.

Asking Dr. A. Neri about the future of the Health System in Argentina, he answered that without a crystal ball is difficult to make a prognosis. But nevertheless he points out that there could be two scenarios. The first one is what he described as a hypothesis of disaster. The current critical situation will continue and the deterioration of all the players in the Health System will be dramatic. There will not be any structural changes and the anarchy will preserve the fragmentation and the lack of control increasing the inequity within the people in the System. The players, Government, HMOs, Pharmaceutical Industry and Physicians will be fighting for their own interests and going through a Darwinian process, so that only the strongest will survive.

Once the crisis is overcome, Dr. Neri points out that all the groups of power (Trade Unions, Professionals, Pharmaceutical Industry, State Bureaucracies) in the Health System will be weakened by the crisis and that is the opportunity from the Government to try to make some necessary changes. In this weakened scenario, the players tend to be more flexible. If that does not happen, all the players will begin fighting against each other to gain some competitive advantage but the result will only be a draw. Neri believes that these groups of power have no creativity to change anything but they are strong in struggling to maintain the "status quo". Neri remarks that the bureaucracies of the State, which talk much about defending the Health of the population, are defending actually the status of the public employee. Their speech, which seems to be progressist, is actually neo-populist.

So that if at the beginning of the reactivation, "the Minister of Health is intelligent and take the reins of the situation, there could be a big chance for the improvement of the Health System"(Neri). The basis, which the Radical Party thinks that the change

should come, is different from the Peronist Party in one thing; Radicals think that the whole Health System should be decentralized geographically giving the management and control of the beneficiaries to the Provinces. There would be a Provincial Insurance similar to what the Peronists proposed but Provincially managed. This insurance should regroup the people according to where they live and not to which trade they belong. This Insurance will be universal, covering the people under HMOs and also those who are out of the formal system.

1) Provincial Insurance:

All beneficiaries of this Insurance will have the same rights so that there will not be difference between the affiliates. The affiliates should be free to choice between a list of Health Providers, which will be the same for all the affiliates. If someone wants to have an additional coverage, like better Clinics or free choice of physicians, he or she should pay for it additionally to the Provincial Insurance according to Neri. "This provincial HMO should incorporate the affiliates to the Board to make sure that the interests of the affiliates are considered" (Vasallo). "HMOs should be controlled and regulated by the Central Government" (Vasallo).

Usually there is in each Province a big HMO for the Public Employees or a strong Ministry of Health with some kind of System of Health Coverage. The aim is to give this HMO the total control of their province and take advantage of the economies of scale as it is the biggest of the Province and has the structure and knowledge to provide Health Care. There are some provinces, mainly in Patagonia, which the HMO is not that solid and it should be done by the Ministry of Health suggests Neri. The Provincial HMO will have a complete list of the providers of Health Care in its territory and could get better conditions (price, service, etc.) than when the Health System is fragmented in different HMOs. Fragmentation brings overcapacity in the Health provider sector. Dr. Neri pointed out that there is a physician every 100 people, which is too much regarding the population and infrastructure. With the reorganization, the system will be more efficient and there should be some

kind of restructuring of the provider sector to meet the demand. This restructuring "could prove to be painful for this sector increasing the unemployment within physicians and Clinics will be closed"(Neri). On the other side the prevailing Health Care providers will regroup to be more competitive and they could be Public (Hospitals), Mixed or Private. Affiliates will be free to choose within these providers. A new policy should be introduced regarding the practices. Nowadays patients are free to go directly to the Specialist increasing the costs for all the System as Specialist fees are more expensive than the ones of GP's . There will be different levels of attention: the first one will be Primary Care with the GP's taking the consultation and sending the patient to the specialist (Second Level) if needed. Dr. Neri also thinks that, as the PMO from the Peronists, there should be regulation stating which practices will be covered by the Provincial Insurance and which drugs will get a discount.

The National HMOs, mainly the Trade Unions and the Armed Forces will sub-contract the service in that province paying to the Provincial HMO. The affiliates to PAMI, the retired people, will also be included in the Provincial HMO. Smaller National HMOS, which cannot survive, will be eager to merge with the Provincial HMO or a bigger National one. The Ministry of Health of each province will do the Control of the Health Care provided. There is the reluctance of the Trade Unions to give their affiliates and resources to the Provinces as the Trade Union HMOs will disappear and the funds will be diverted to the provinces. The main concern for the Central Government according to Vasallo is that the Governors coveted this initiative more from the point of view of having extra funds from HMOs and the Government for the Province, than from a Managed Care improvement of the health of their population. That is also the reason why the Central Government is suspect of the success of this initiative as it thinks that those extra funds will be used for another purposes than providing better Health Care.

The aim of this approach is to concentrate the Health Care in bigger HMOs, provincial ones, with national guidelines and rules, providing a better service. This HMOs should implement, regarding to C. Vasallo up to date Managed Care practices to improve the quality of life of the population. Both Dr. A. Neri and C. Vasallo stated that laws issued by the Parliament should validate all these changes.

2) Public Hospital:

Which is the role of the Public Hospital in this new scenario? Hospitals should be decentralised and it cannot be like now that there is National Hospital, a Provincial Hospital and a Community Hospital in the same neighbourhood. Provinces should be responsible for the Hospitals in their districts. They should have full time physicians who dedicated themselves to these Institutions and not part-time as today. A validation of the title should be performed every certain period of years, leaving the best professionals in the practice. The challenge will be how to manage the cooperation between private providers and Public Hospitals. Some parts of the Country like parts of Patagonia where the Public Hospital is the only provider of Health Care seem no problem but in urban centres there is a competence between the Public Hospitals and private providers. Some Hospitals will specialize in a certain field and there will be a segmentation of the Public attending this Public Hospital. There should be some body of control that certifies the Health Care given in the different Hospitals and Clinics to make sure that standards of quality are achieved.

3) Catastrophic Diseases:

Regarding the Catastrophic diseases there are different point of view between Dr. Neri and Vasallo. Vasallo believes that those patients who have one of these diseases should be treated by the State in a special program but not related to the HMO. The HMO, provincial or national, should not cope with the economic burden of those patients. This opinion is the same as the

enunciated by the Peronist Party, Vazquez and Tobar. On the other side, Dr. Neri, thinks that there should be no discrimination. In one family you will have the whole family belonging to a certain HMO. If one member of the family has got AIDS and he or she is excluded of the HMO and sent to another Health Care Provider, this member will feel as an outcast. This case of AIDS is illustrative of what can happen making almost impossible to preserve the secrecy of the status of that patient increasing the stress of that person. When all the family belongs to the same HMO, all of them will go to the same physician and be treated equally. The economic burden of those patients should be afforded by the State but not excluding this people of their own HMOs. The State would make an additional funding for those cases.

4) PAMI:

What about PAMI? For both respondents, PAMI is not sustainable. PAMI has always been seeing as something apart, different from the other HMOs. It has the population with higher costs for the HMOs and now it there is a problem of funding which cannot be solved. It is impossible to get enough funds so that the crisis is inevitable. Vasallo believes that the main problem of the PAMI is mismanagement and corruption. There is no control about practices and money is dilapidated without reason. For example, a lot of patients are referred from the provinces to Buenos Aires for surgical procedures. Those patients could be treated in their own provinces but if it is done so, the regional office of PAMI would not have the funds to pay for the surgical procedure so that it is easier to send them to Buenos Aires as PAMI Central will pay for everything. The cost of each patient by PAMI is high. "If each pensioner could get that money from PAMI, he would be able to contract a private insurance"(Vasallo).

According to Dr. Neri and Dr. Vasallo, PAMI should be decentralized and given to the Provinces, but they refer that there is no political will from the Government to do so. Some issues like medicines could be still centralized because of efficiency. A trial could be done in two or three provinces to see if

it works. If it works, the Provinces HMOs should take it. The Provincial HMO, PAMI and the people not covered by any HMO, mainly the poor, account for 85% of the population of the provinces. If the Provincial HMO contracts private providers and Public Hospitals, health care could be given rationally. If the affiliates to PAMI are in the Provincial HMO, the Central Government should pay them a certain amount of money per affiliate. Only high technology procedures should be paid apart by the State as Transplants.

5) Structure of the State within the Health System:

Having all the Health Care in hands of the Provinces, the Ministry of Health, will act only as a control body in coordination with the COFESA (Association which includes the Ministry of Health of all the provinces) The Ministry of Health will provide the guidelines and rules to the provinces. It should also coordinate the flow of funds between the Ministry of Economy and the Provinces HMOs.

Regarding the central purchase, the Radicals think that the purchase should be done decentralised to avoid high inventories and mismanagement. There should also be training for the Purchasers to do it more professionally.

How will be the Health System financed? It would be done on a mixed way. Part of the income will come from the employees and employers as it is done currently but another part will be coming from the state. So that each province will be receiving the funds from the State, according to the number of the affiliates from PAMI, Catastrophic Diseases and Provincial HMOs. The distribution will be made by the State according to the population of each Province and the pathologies that are prevalent. The way of collecting taxes should also be changed, making responsible the Provinces from the taxes that are collected contrary to the current system where the big load of taxes is collected by the Central Government.

6) Vademecums:

Which is the attitude of the Radical Party regarding Vademecums? There is discrepancy between Vasallo and Neri in this point. Both think that a basic list of drugs should be issued and it should be followed by the HMOs. The difference is that Dr. Vasallo thinks that the HMOs could adapt this list to their needs and the pathology of their province and include some other products, while Neri thinks that there should be a unique list issued by an External Body and followed by all HMOs. Regarding which products to be included from the drugs that appear in the PMO (Compulsory Medical Care), there could be an attitude in favour of Generics but the position of both respondents is not definitive. The Vademecum according to Neri should be done by a Scientific Committee who decides which new drugs and new practices will be introduced. The creation of the Committee should be approved by the Parliament. Only therapeutic advances could be introduced. The Vademecum should be constantly revised and updated. This committee would not only control drugs but also products, which can be included in the Vademecum, assuring the bioequivalence and bioavailability of the products. The products should be proved in patients and should provide a Clinical Benefit. Efficacy and Adverse Reactions should also be tested. The members of the Scientific Committee should be highly qualified for the job and they should be elected because of their merits and not by political nepotism.

Point of View of Pharmaceutical Industry

The point of view of the Pharmaceutical Industry is more focused on the issues relating to drugs and generics than in the Structure of the whole Health System but their view is somewhat different from the previous ones.

When asked about how the Health System will change in the next 5 years, Mr. E. Felicio remarked that although some sectors of the economy in Argentina have changed considerably in the last 10 years, the Health System suffered almost no change. What was the reason? Mr. Cavallo issued a decree during the Presidency of

Dr. C. Menem aimed at deregulating the Health System. The decree allowed affiliates from one Trade Union HMO to switch to another Trade Union HMO. It did not permit them to switch to a Private HMO. This issue was also requested by the World Bank in order to give more loans for the restructuring of the Health System. But this deregulation was not favourable to the bosses of the Trade Unions, as they did not want to loose affiliates and resources; so that after the decree was issued in February 2000, the politicians of the Peronist Party blocked the implementation of it. There have been always close ties between the Trade Unions and the Peronist Party. So that in the end there was effectively no change.

1) HMOs:

But now the severity of the crisis is of such magnitude that it could provoke a change in the Health System by necessity but even then Mr. Felicio thinks that there are few probabilities that the current structure will change. As said before, the Trade Unions are closely related to the Peronist Party, which is now in power and would be re-elected in the next elections, which will be taking place in 2003. For the Trade Unions a change in the rules of the HMOs and the Health System is not desirable. So that they will induce the Government to maintain the "status quo" as they have done for the last 10 years. The Government is keen to accept this issue as they have the Trade Unions as allies in other fronts.

In spite of this fact, there has been a consolidation of HMOs during the last years. In Argentina, the minimal acceptable amount of affiliates to be operational is 100.000. Those HMOS, which were too small, have merged with bigger ones. In February 2000, there were 365 Trade Union HMOs and now there are only 250 HMOs. There is also a proposal of the bigger HMOs to share some services or make a pool for purchases of medicines and equipment but political issues have blocked all these initiatives. In the near future, Mr. V. Quiñones thinks that the funds of the Trade Union HMOs will come from the contribution of the employers and employees but the State will not contribute to fill the gap between

income and expenses. The State will be devoting all their resources to support the Hospitals.

Regarding the Province HMOs the situation is somewhat different but with the same conclusions. The Province HMO is independent and it will like to maintain itself in this way. The Governors will not accept to be told what to do by the Minister of Health. The Minister should get a consensus in COFESA (Association of the Ministers of Health from the provinces and state) to implement his plans. The Provinces HMOs account for a great number of the votes so that the Governors, Radical, Peronist or Independent, will not let the Central Government have a say in what should be done.

2) Public Hospitals:

An issue that will concentrate all the efforts of the Government, financial and in terms of time will be the Public Hospital. As unemployment grows and recession deepens more people loose their health coverage and they go to the Public Hospital. The Government has to implement new ways of providing Health Care and medicines. Neri remarks that a change is already occurring, so that more full time physicians are at the hospital. The demand of Health Care in the Public Hospital has increased but not proportional to the amount of people out of the HMOs. The reason for that is that the people who are sick stay at home because they do not have the money to go to the Public Hospital and buy medicines. But as soon as there is a slight reactivation, the demand will increase and the Public Hospitals will have to cope with increasing amount of people.

2) PAMI:

The current responsible for the PAMI, Dr. Corchuelo Blasco intended to decentralise the PAMI and give the affiliates to the Provinces HMOs, more in concordance with the opinion of Dr. A. Neri and Dr. C. Vasallo. But there was strong political opposition from the Peronist Party in the Parliament. He was criticized by his colleagues (he is himself a deputy) as he was signing treaties

with the Provinces to dissolve PAMI. Previously to be in charge of PAMI, he had voted a law that legislated that PAMI should be an independent HMO and that it could not be dissolved. Mr. V. Quiñones suggests that, according to the history of PAMI, it will be very difficult to introduce any changes in this HMO. It represents also a huge amount of votes (15% of the total) when it comes to elections and the few changes that could be introduced will be only cosmetic.

4) Catastrophic diseases:

A centralised organism buying medicines and health services for this type of patients will make the whole system more efficient according to Quiñones. The cost of these patients is too high to be afforded by an HMO. Regarding the Pharmaceutical Industry, prices of products for these patients will go down but the amounts requested will be higher and there will be more patients with adequate coverage. Nowadays there is a big spread between prices sold to different customers. When purchases are centralized, everything will come to a referral price and the cost for the whole system will be lower. The only issue that is critical so that the whole system is efficient is the control of prescriptions. Having these type of products a high price, there is some room for fraud. So that the Industry could help in the validation of the prescriptions to make sure that the patients are real and that they are treated. The Pharmaceutical Industry has already done that in the Oncology Market for PAMI with great success. Quiñones believes that the Control in this case should be done not by the Government, or by the Health Providers but by the Pharmaceutical Industry.

5) Vademecums:

The opinion of Quiñones is that the same diversity of approved practices found in Trade Union HMOs, Province HMOs and Private HMOs, will also be found in the Vademecums. The Minister of Health will try to impose its own Vademecum but each HMOs will decide what to do. The Government has issued now its Vademecum in the PMO, which should be compulsory for all Trade Unions HMOs. This Vademecum will be accepted by the HMOs but each one will adapt

it to its own reality. There is no consensus within the players in the System to follow strictly the Vademecum of the Government. The Pharmaceutical Companies will continue with its lobby actions to introduce their products in these Vademecums.

6) Generics:

The Government is trying to implement a policy of generics copying the Brazilian model. The main difference is that the Generic of a product in Brazil has to go through studies of bioavailability and bioequivalence, which are costly. The few companies that in Argentina manufacture generics do not have those studies. So that we cannot speak about Generics but Similar. There is also a difference in Argentina that there are strong national companies with copies of the products of the multinationals but they are not regarded as Generics as they have the same price as the products from the multinationals. What the Government is trying to promote are products with no trademark that are cheaper and can be afforded by the impoverished population. The head of the ANMAT (FDA in Argentina) Dr. Limeres told in a conference in Washington D.C. that "quality should be sacrificed for price".

Quiñones thinks that this policy will have some effect in the future and the impact of these generics in the market will be a decrease in prices of around 40%; sales volume will increase but it is hard to estimate in which degree. The generics market share is only 2 to 3% now in Argentina and the main purchaser is the Public Hospital market as products are interchangeable. The Generic Companies are small, with lack of Working Capital and with bad quality control and manufacturing practices. They are not big competitors to the other companies in the market. But there is a trend of big companies, Roemmers, Novartis and GM, to buy small generics companies. There are also two multinational generic companies, which came to Argentina in the last years, Hexal and Ivax. Those companies will gain much from the promotion of the generic policy introduced by the Government. If the world market is considered, Generics account for 20 to 25% of the total market, much more than the 3% that they have in Argentina. So

that the Industry considers that the promotion of Generics by the Government will be a new reality in the next 5 years and it will change the commercial practices.

Conclusions

Both Peronist and Radical Party believe that in the next 5 years there will be first, a period of recession with no changes in the structure of the Health System, and afterwards a reactivation process in which necessary changes had to be introduced. The Pharmaceutical Industry expects no changes in the future, except for Generics, supporting this idea in an historical perspective. This believe is based on the fact that every time that the Government wanted to introduce a change in the Health System, the groups of power fought against it and the situation for the players never changed. As Dr. Neri pointed out, these groups of power are strong in struggling to maintain the "status quo".

As soon as the reactivation process begins, both the Peronist Party and Radical Party want to introduce a Universal Health Insurance for all the inhabitants. The difference between both parties is, that the Peronist Party will leave the HMOs Structure as it is and it will only give some Health Care to the poor in the Public Hospitals. There will be more medicines available for the poor in those Institutions.

The proposal of the Radical Party is more comprehensive as the Provinces HMOs get all the affiliates from the Trade Unions HMOs, PAMI, Armed Forces and people out of the formal System. The services provided will be the same for all the population, independent of income. Both Parties think that this Insurance will be financed by the contribution of the employers, employees and the State, but the Pharmaceutical Industry has its doubts that the State could finance it, as it will be devoting all its resources to the Public Hospital.

The restructuring of the Public Hospitals has been studied thoroughly by the Radical Party to be able to compete in the new scenario with the private Clinics. Physicians should be full time employed and validation of their titles every five years should be introduced. Managed care practices should be implemented regarding practices. The

Pharmaceutical Industry sees the Public Hospital as the greatest issue for the Government in the near future as increasing numbers, due to unemployment, call at the Public Hospitals for Health Care. The Peronist Party does not consider the Public Hospital a big issue although Tobar thinks that certain Managed Care practices should be introduced.

There is also discrepancy between the Peronist Party and the Radical Party regarding the Centralised Body for purchases. The Radical Party remarks that having it decentralised is more efficient and it is more near to the customer. The Peronists talk about savings being done; the Industry sees only as a Market opportunity as historically the Centralised Body buys more than it actually uses.

Almost all respondents think that the Catastrophic Diseases patients should be included in a Special Insurance, which will provide Health Care to these patients. Only Dr. Neri has a different approach, looking more from the perspective of the patient and the family. The patient should stay in his or her HMO and be treated by the providers of this HMO, so that the patient will not feel excluded of his family group.

PAMI should be more efficient according to the Peronist Party but it is not clear how this tremendous task will be tackled. The Radical Party believes that PAMI should be dissolved and its affiliates given to the Provinces HMOs. Felicio, from the Pharmaceutical Industry, believes that PAMI will continue as it is. He claims that the political interests within the Peronist Party to preserve it are so strong that the idea to dissolve, proposed by the Radical Party, will never have political support.

Generics will be an issue in the next 5 years, specially affecting the Pharmaceutical Industry. The Peronists have introduced a new Generics Policy aimed at making medicines affordable for the people. This policy has not been so successful because the current Generic Companies in the Market were not prepared for this change, lacking resources and knowledge according to Quiñones. Nevertheless, the Pharmaceutical Industry believes that Generic Companies will catch up and new entrants, both National and Multinational, will increase the share of Generic Products

in the Market. About this issue, the Radical Party put more emphasis in quality control of practices and medicines than in the issue of promoting a Generics Policy.

Regarding Vademecums there are there are two lines of thinking, not related to the Parties. Tobar and Neri think that there will be only one compulsory Vademecum for all HMOs. Vazquez, Quiñones and Vasallo, think that there will be a basic list of drugs and each HMO will adapt it to the characteristics of its population. Both parties believe that Pharmapolitics jobs will be preserved by companies to have their products introduced in these Vademecums. Neri suggests that the rules to introduce the products will be stricter so that the Pharmapolitics Managers will have to become more professional in terms of Pharmacology and Pharmaeconomics.

So that what will happen in the future with the Health System, is a question mark. At least there are some interesting ideas from both Parties to be implemented. The outcome will depend on how fast the economy reactivates, which will the Government Policy in terms of Health, how is the share of seats in the Parliament between the parties and how the players in the Health System adapt to this new scenario.

Pharmacopolitics: Pharmaceutical Industry's influence in Politicians and Managed Care Settings

Author: Javier de Renteria

December 2002

Pharmacopolitics: Pharmaceutical Industry's influence in Politicians and Managed Care Settings

Introduction

The term Pharmacopolitics or Pharmapolitics has been defined (Quiñones, 2002) as the activities performed by the Pharmaceutical Industry aimed at influencing Government, Public Officials and Health Management Organisations (HMOs) or Managed Care Organisations (MCOs) in order to get a competitive advantage in the Market. There has been no research in this topic in Argentina, and the first mention of this term in the literature is done by Cerasale (2000), claiming that it has become a popular word together with Pharmaeconomics but instead of explaining its significance he continues the paragraph describing the advantages of Pharmaeconomics. The second mention in the literature is done by Tobar (2002) referring to Pharmacopolitics as the twin sister of Pharmaeconomics but again there is no explanation of its significance and scope.

Redwood (1997) refers to Pharmacopolitics as the policy implemented by the Pharmaceutical Industry according to the political environment, regarding innovation, location (Redwood, 2002) and cost-containment procedures. Redwood focuses in the cost-containment policies implemented by the Health bureaucracies and describes its flaws. This definition of Pharmacopolitics does not correlate with the definition of Pharmacopolitics accepted in Argentina; Redwood definition describes the influence of the political scenario in the decisions taken by the Pharmaceutical Industry.

Vasallo (2002) argues, the American Health System is more similar to the Argentine one than the European, being Health considered a private good which depending in the purchasing power of the individual, could be obtained or not, so that due to the lack of literature in the Pharmacopolitics subject in Argentina, the American Health System will be considered to review the two more important activities of Pharmacopolitics:

a) lobbying Congress and the Government performed by the Pharmaceutical Industry.

b) the influence of the Pharmaceutical Industry in HMOs/MCOs regarding Formularies, called Vademecums in Argentina.

The Nature of Lobbying

Definition:

The Oxford English Dictionary Online (2002) defines lobby:

“1. to influence (members of the house of legislature) in the exercise of their legislative functions by frequenting the lobby. Also, to procure the passing of (a measure) through Congress by means of such influence”

“2. to frequent the lobby of a legislative assembly for the purpose of influencing members’ votes; to solicit the votes of members”

The Merriam-Webster Dictionary (2002) introduces a new fact to the definition “influencing public officials “ broadening the target of lobbying and not limiting it only to the legislators. It also defines that is an influence “toward a desired action”. It confirms that there is an objective to be reached.

In the USA, lobbying per se constitutes a lawful opportunity available to interest groups to exert influence and to have an impact on policy. The right to lobby (Jobst, 2002) is implicitly derived from the First Amendment of the USA Constitution, which states “Congress shall make no law [...] abridging the freedom of speech or of the press; or the right of the people peaceably to assemble and to petition the Government for redress of grievances”. The rationale of lobbyists stems from the belief that a democratic society does not necessarily guarantee equal access of individual opinion, and hence, any tool to foster awareness of the legislators about certain topics should be allowed. As Lord (2000) refers, legislators “face a lack of knowledge about constituents relevant public policy priorities and preferences” due to limited personal and staff time and resources. Lord also confirm that legislators must rely to a great degree on the information that they receive from the different lobbyist groups to make decisions in the different subjects.

The classification of lobbying

Regarding the different types of Lobbying, two different perspectives could be found in the lobbyists arena. (Suranovic, 2001):

- a) Casual lobbying: it occurs when a person uses their leisure time to petition or inform government officials of their point of view. In these cases there is no opportunity cost for the economy in terms of lost output, although there is a cost to the individual because of the foregone leisure time.
- b) Professional Lobbying: occurs when an individual or company is hired by someone to advocate a point of view before the Government. That could be the case when a Pharmaceutical Company hired a Lobbying firm to push some deals through Congress.

The classification done by Suranovic is rather simplistic as it does not take into account a lot of diverse types of lobbying restricting it to the casual or to a professional one. There are other types of lobbying groups as the Political Action Committees (PAC), Interest Groups as Public Citizen's Congress Watch, and also the Corporate Constituency-building as means of influencing the legislators. Political action committees (PACs) are set up by corporations, unions or other organisations to act as conduits for funds to candidates who favour particular policy positions (Oxford Dictionary of Politics, 2002). Interest Groups (Oxford Dictionary of Politics, 1996) are organisations seeking to advance a particular sectional interest or cause, while not seeking to form a government or part of the government. The term is often used interchangeably with pressure group. There is also the Corporate constituency-building with lobbyists inside the Corporations, named in-house lobbyists (Oxford Dictionary of Politics, 1996), to differentiate themselves of contract lobbyists from Consulting or Law firms.

The characteristics of lobbying

Even if Suranovic (2001) classification is simplistic, he argues that lobbying is essentially distributive in nature, since the lobbyists income will derive from the losses that will accrue

to others in the event that the lobbying effort is successful. This definition is important to the research as lobbying is an activity that does not create value for the economic system. It only transfers value from one part of the system to another. Another name given to professional lobbying in the economics literature is a “ Directly UnProductive Activity” (Suranovic, 2001). This term is biased through the tarnished reputation of lobbying. That is related to the “ scandals in which lobbyists employed questionable tactics to win legislation for special interests, acquiring a sinister image” (Oxford Guide to the United States Government, 2001). There are plentiful articles written about Lobbying and Corruption, which claim “ criminal methods such as bribery and blackmail” (A Dictionary of Economics, 1997), but corruption is not the focus of this research.

Lobbying is also called rent-seeking, a term coined by Anne Krueger, 1974, (Oxford Dictionary of Politics, 1996), as it is seeking to capitalise on the scarcity value of a good or service. The fees paid to the lobbyists come from a pool of funds that arise when the lobbying activity is successful.

Lobbying is a necessity for the democratic system to work. Somehow information about preferences and desires must be transmitted from citizens to the Government officials who make policy decisions. Since everyone is free to petition the government, lobbying is the way in which government officials can learn about the desires of their constituents (Suranovic 2001).

Pharmaceutical Industry's Lobbying

The perspective of the Pharmaceutical Industry

No paper has been written by the Pharmaceutical Industry about its lobbying activities in the USA. The only written information is the speech given by Alan F. Holmer (2002), President of the Pharmaceutical Research and Manufactures of America (PhRMA) in its Annual Meeting (2002). PhRMA is the Chamber which comprises the Pharmaceutical Companies in the USA; those companies account for generics companies are not members of PhRMA.

Holmer stated that the PhRMA strategy was divided in two different fronts:

- a) advocacy programs: Holmer's objective was to make PhRMA "the premier advocacy organization in the world". To achieve this objective advocacy programs are run from PhRMA's eight regional offices and PhRMA is represented in 50 state capitals by people from both political parties, Republicans and Democrats. "These are representatives of local citizens, know the legislators well, and understand how our issues will be considered in their states". PhRMA have also six ally development people in the regional offices, that have contacted labour leaders, small business owners, physicians, nurses, pharmacists, minority groups, patients and patients advocates. Alliances have been made with these groups aimed at achieving common goals.
- b) federal lobbying: The federal lobbying team of PhRMA amounts to 17 people. Those are the in-house lobbyists. Some former congressional staff was included in PhRMA's payroll as Rodger Currie (Common Cause, 2001) being one of the leaders of the PhRMA team of lobbyists (Holmer, 2002). According to Holmer, the team has achieved outstanding results as banning a law on re-importation of drugs to the USA. As the medicines manufactured in the USA are sold at cheaper prices in other countries due to price controls in other countries (Common Cause, 2001), there was an initiative for issuing a law allowing pharmacists and drug wholesalers in the USA to re-import prescription drugs. This initiative was blocked by the lobbying performed by PhRMA as Holmer relates "Two years ago, on re-importation, 12 members of the House voted no. Last year, the number of opponents had increased from 12 to 267."

In all his assertions, Holmer denotes triumphalism with sentences like "but one organisation never loses, and that organisation has hundreds of victories to its credit and zero defeats in the United States Congress, and that is the pharmaceutical industry." The speech given by Holmer, does not describe how lobbying is implemented or financed in Washington or in a regional basis but these topic are well documented by several interest groups or pressure groups.

The Research done by Interest Groups

Common Cause (2001) and specially Public Citizen's (2001) have elaborated an extensive literature describing the strategy, the resources devoted and the achievements of the Pharmaceutical Industry in Washington. It should be pointed out that even if the information is based in reliable data, as lobbying investments done by companies should be disclosed every year since 1995 (Public Citizen, 2001), the opinions of these groups are biased towards the objective they defend. Phrases as " This industry, however, racked up its successes at the expense of the American public" (Common Cause, 2001), or " Public Citizen believes that no bribes should be given to the drug industry." (Congress Watch, 2002) are common so that the researcher will focus on the facts more than in the opinions that are enunciated. In the introduction of its report "America's Other Drug Problem: A Briefing Book on the Rx Drug Debate", Public Citizen Congress Watch (2002) states that "some readers may see a pro-consumer bias in the selection of facts. That bias may well exist." But in the creation of the report, " we have used credible, independent sources and the most current data that we know of for each and every point we make." (Congress Watch, 2002).

According to Public Citizen's Congress Watch (2002), the pharmaceutical industry is one of the most potent political forces when it comes to influencing legislation in Washington. Through inside-the-beltway lobbying, campaign contributions, issue ads, funding front groups, and conducting grassroots lobbying, the industry largely gets what it wants from politicians in Washington. Common Cause, a citizen's grassroots lobby dedicated to making government more open, honest and accountable at the national, state and local levels, declares in its report " Prescription for Power" (2001) that PhRMA and its member companies have spent at least U\$S 256 million on lobbying Congress, the White House and federal regulators over the past five years (January 1,1996- December 31, 2001), according to federal lobbying reports. This information does not match with the figures provided by Public Citizen's Congress Watch Report (2002) which reports an estimate of U\$S 403 million for the period 1997 to 2001. Public Citizen's Congress Watch reports have a sound methodology and a complete list of references. Common Cause report, has very few references and the methodology of obtaining the information is not described so that

Public Citizen will be considered for raw data and Common Cause information will be added to complement the information provided by Public Citizen and other sources.

Structure of the industry's lobbying

Public Citizen's Congress Watch describes that the Industry hired 623 lobbyists in 2001, 340 of them called "revolving door lobbyists" as they were previous members of the Congress (23), staff or executive branch employees (317) and have special access to the current Members of the Congress. From the rest of the 623 lobbyists, (Public Citizen's Congress Watch, 2001) 165 lobbyists were in-house lobbyists during the year 2000. They worked for the pharmaceutical companies and its two major trade associations, PhRMA and the Biotechnology Industry Organization (BIO). All the pharmaceutical companies, considered in the report, spent more than U\$S 1.000.000 on lobbying in 2000. The 10 Top companies in lobbying expenditures in year 2000 were American, followed by Glaxo Wellcome and Smithkline Beecham; this fact shows the acceptance of the American Companies towards the activities of lobbying Congress and the Government.

During the 2002 election cycle, the prescription pharmaceutical industry has given 74% of contributions to Republicans and 26% to Democrats. (Public Citizen's Congress Watch, 2002). According to Common Cause (2001), the industry increasingly allied itself with the Republican Party, which it perceived as more supportive of its goals, and which took control of Congress in 1995; nevertheless, the pharmaceutical industry continued to cultivate some key Democrats, as Senator Joseph Lieberman or Senator Robert Torricelli (New Jersey), state which has a concentration of pharmaceutical companies in it.

Methodology

The methodology of executing its lobbying demonstrates a high degree of sophistication. The traditional method is to donate campaign contributions in the election cycle so that in the 1999-2000 election cycle, pharmaceutical manufacturers contributed with U\$S 20.1 million (Public Citizen's Congress Watch, 2001) to the political campaigns. There has also been an increase of soft money, which are unlimited donations to PACs (Political Action Committees) controlled by Party leaders. Fifty nine percent of the industry's campaign

contribution in 1999-2000 were in soft money. (Public Citizen's Congress Watch, 2001). The pharmaceutical industry also contributed to the inauguration committee of President George W. Bush with U\$S 625.000, establishing a relationship that later collected its rewards as Mitch Daniels (Eli Lilly) runs the Office of Management and Budget, Donald Rumsfeld (Searle) sits in Bush Cabinet and a one time pharmaceutical industry lobbyist, Nick Calio, is Bush's chief liaison to Congress (Public Citizen's Congress Watch, 2001).

Another vehicle to support the Pharmaceutical Industry's lobbying efforts is "Citizens for Better Medicare". According to Congress Watch it is a sham interest group created in 1999 to oppose the drug policies against the industry. The objective of Citizens for Better Medicare as it enunciated in its web site is to pursue basic consumer fairness in health care (Common Cause, 2001). Using Citizens for Better Medicare, the pharmaceutical industry spent U\$S 50 million in 1999-2000 on ads, aimed at supporting or attacking candidates which might help the interests of the Pharmaceutical Industry; Citizens for Better Medicare first wave of ads were modelled on the Harry and Louise film and aimed at opposing the Clinton health care plan on Medicare in 1993-1994 (Public Citizen's Congress Watch, 2002). The advantage for the Pharmaceutical Industry is that Citizens for Better Medicare spending was kept secret under Section 527 of the federal tax code, which covers groups whose purpose is to influence or attempt to influence elections. Shortly after Congress closed the 527-loop-hole, Citizens for Better Medicare became a different kind of tax-exempt group- a 501(c)(4) non-profit. Under this category, Citizens for Better Medicare does not have to disclosure contributors or spending details. (Public Citizen's Congress Watch, 2002). This kind of tricks helped to preserve the anonymity of the Pharmaceutical Industry, although there are indications that establish its relationship. Tim Ryan, its Executive Director, was previously Marketing Manager for PhRMA (Common Cause, 2001).

Additional to Citizens for Better Medicare, the pharmaceutical industry also contributes with the US Chamber of Commerce and with the United Seniors Association. (Public Citizen's Congress Watch, 2002). United Seniors Association spent U\$S 12 million on issue ads from March 2001 to July 2002 aimed at promoting President's Bush and House

Republican leaders' prescription drug plan, funded in part by PhRMA (Public Citizen's Congress Watch, 2002).

Strategy

The Pharmaceutical Companies' strategy regarding lobbying has concentrated in three issues: protect themselves against competition, preserve a freedom in establishing the prices and tax breaks which improved the bottom line.

Protect themselves against competition

The most influential way of protecting themselves is through the growth of patent life for drugs as patents create a monopoly for pharmaceutical companies (Congress Watch, 2002). Vasallo & Sellanes (2002) refer to patent protection as the most serious adverse effect for consumers due to this limitation to the surge of new suppliers in the Market. It is paradoxically protected by the Government who has the power of issuing and enforcing anti-trust regulations and also the power to create these drug monopolies. This issue is critical for those new drugs aimed at terminal diseases as Cancer. Common Cause (2001) claims: "Even though Bristol Myers Squibb and other companies have compassionate care programs to give these expensive life-saving drugs to some impoverished patients, critics claim that the high cost of these drugs has continued to pose terrible financial burdens on many cancer victims. "There are people with second, third, and fourth mortgages on their houses to pay for this," Jeffrey Kraws, a pharmaceutical analyst for Gruntal & Co., told the Miami Herald. "This isn't cough medicine. People are dying." This type of stories could be heard all over the world and fosters the prejudice of consumers against the Pharmaceutical Industry. This issue is contested by Holmer (2002) as he transfers the responsibility to the Government as patients ask politicians, "Am I still sick because there is no cure, or because my Government has just said "no new medicines for me"?". It is the eternal fight between the payers (Government, Managed Care Organisations) and the Pharmaceutical Industry blaming each other for the imperfections of the Health Systems as it is. Even then, patents are necessary for the Pharmaceutical Industry to be able to invest million of dollars in research and development to find new molecules.

The effective patent life of a drug in the USA averages 13.9 to 15.4 years (National Institute for Health Care Management, 2000). Since the mid-1980s, the federal government has adopted a number of laws that extended the effective lives of drug patent by 4.4 to 5.9 years. The major laws and the years they have added to the patent life of drugs are (Congress Watch, 2002):

- 1) The Hatch-Waxman Act of 1984 added, on average, 2.3 years to the patent life.
- 2) The prescription Drug User Fee Act of 1992 increased the efficiency of FDA drug review and approval and knocked 1.2 years off the review and approval process.
- 3) The Uruguay Round Agreements Act of 1994, an international trade agreement, added 1 year to the effective patent life.
- 4) The Food and Drug Modernisation Act of 1997 reduced the average number of years for clinical study by 1 year; FDAMA also gave six months of market exclusivity to a patented drug if a manufacturer tests the safety of the drug in children.

Those modifications achieved by the lobbying of the Pharmaceutical Companies (Common Cause, 2001), protected the profit of the Pharmaceutical companies. It is estimated that the Uruguay Round Agreements Act costs consumers more than US\$ 6 billion due to delayed access to generic drugs (Congress Watch, 2002), great part of it returning to the Pharmaceutical Industry.

Pharmaceutical Companies stand to lose billions from expiring patents as generics are introduced into the market. It is estimated that the projected sales of drugs coming off patents between 2000 and 2004 are US\$ 25.5 billion. (Congress Watch, 2000). There is a product of Schering Plough, Claritin, which has received a lot of lobbying efforts to prolong its patent life. Claritin sold US\$ 2.3 billion in 1999. Claritin's patent was extended two years by the Hatch-Waxman Act, 22 months under the Uruguay Round Agreements Act and six more months because the manufacturer tested the safety of the drug for children (Congress Watch, 2002). Schering Plough is pushing to extend its patent beyond 2002, backing its request on the fact that the approval of the antihistamine took an unusually long time, nearly 6 ½ years (Manning et al, 2001) compared to the normal 2.6 years approval time. Schering Plough spent US\$ 4.3 million on lobbying to achieve this objective but failed in the last session of Congress (Manning et al., 2001). Common Cause (2001)

referred that “consumer outrage and bad publicity over these patent extension attempts have so far stymied these congressional efforts”. The Prime Institute of the College of Pharmacy (Manning et al, 2001) estimates that a three year extension of the Claritin patent, would cost consumers more than U\$S 5.3 billion.

Lobbying has an effect on patent life growth in the USA, ensuring additional profits for brand-name products during their patent life. The achievement for the Pharmaceutical Industry of the regulation of the six additional months of patent protection given for testing the safety of drugs for children, represent additional profits of U\$S 592 million a year (Congress Watch, 2002).

Preserve the freedom of establishing the prices of the products

Prescription prices rose at more than six times the rate of inflation in 2001 in the USA; the average price per prescription increased 10% from 2000 to 2001, while the rate of inflation was only 1.6% in 2001.(National Institute for Health Care Management, 2002). The reason for this increase in prices is due to several factors (Congress Watch, 2002): more utilisation of popular drugs whose prices are above average, being those aimed at seniors far more expensive than the other ones, and lack of price controls in the USA. Canada, UK or Continental Europe do have price controls and patients pay between 35% and 50% less than in the USA. These benefits in price freedom has been preserved by the industry so as to boost profits. According to Public Citizen’s Congress Watch, USA sales account for about 60% of global industry profits. In other words, Americans pay, on average, 60 cents of every \$ 1 that any pharmaceutical company in the world earns in profits.

Public Citizen’s Congress Watch (2002) states that at the top of the industry’s agenda has been opposition to prescription drug coverage under Medicare and hostility to measures that would moderate rising drug prices. “Worried that the bulk buying power of Medicare would lead to discounted prices in the lucrative senior citizen market, the pharmaceutical industry launched an unprecedented blitz of lobbying, campaign contributions, and so-called issue ads to help its political allies and attack its enemies.”(Congress Watch, 2001) The industry’s political investments have paid off as Congress has failed to provide Medicare

prescription drug coverage (Congress Watch, 2002). Instead, Republican Leaders have promoted proposals that would encourage seniors to get drug coverage through private insurance companies and HMOs, preventing the Medicare program from negotiating substantial price cuts (Congress Watch, 2002). Holmer's (2002) confirms that PhRMA highest priority is to focus all the lobbying resources on "enacting a high-quality Medicare drug benefit for seniors, delivered through the private sector." This reform will leave prices unaltered increasing the demand for medicines as seniors get some kind of reimbursement. Public Citizen (2002) conducted studies in 13 states and major metropolitan areas, which showed that the top 10 drugs used by seniors cost Medicare beneficiaries who are without prescription drug insurance nearly twice as much as pharmaceutical companies' most favoured customers, such as the Department of Veterans affairs. It is also important to notice that seniors are 13% of the population but account for 34% of all prescriptions dispensed.

Tax breaks which improved the bottom line

Public Citizen's Congress Watch (2002) refers that the tax rates for the pharmaceutical industry are much lower than other industries as the effective tax rate averaged 16% from 1993 through 1996 compared to 27% for all major industries over the same period. The pharmaceutical industry used tax credits to cut its taxes by almost \$ 28 billion from 1990 to 1996 (Public Citizen's Congress Watch, 2002). The savings came from five federal tax provisions: the foreign tax credit, the possessions tax credit, the research and experimentation tax credit, the orphan drug tax credit and the expensing of research expenditures (Public Citizen's Congress Watch, 2002). The research and experimentation tax credit, originally, enacted in 1981 as a temporary measure, has been extended 10 times, most recently in 2000, when Congress gave it a five year reprieve. The 20-percent credit rewards research spending above a certain base level.(Common Cause, 2001). The pharmaceutical industry has also taken advantage of a tax break for companies that built factories in Puerto Rico. From 1980 to 1990, the General Accounting Office (Public Citizen's Congress Watch, 2002) estimated that 26 Pharmaceutical companies had tax savings of U\$S 10.1 billion thanks to the Puerto Rico facilities. There were several attempts to eliminate this particular tax break named Section 936. "The fight to retain the section 936

credit consumed more lobbying and more political capital than all but the biggest ticket items in the proposed deficit reduction bill according to The Washington Post.”(Common Cause, 2001). In 1996, Congress did vote to eliminate this particular tax break, but Members did so on the drugs companies’ terms. The tax break would not apply to any future investments in Puerto Rico but current investments would have 10 years until the tax break would be completely eliminated. That gradual phase-in represented a victory for the pharmaceutical lobby (Common Cause, 2001). These lobbying for tax breaks have given the pharmaceutical industry a sustained competitive advantage over other industries.

Economic impact of lobbying

This lobbying made in Washington and in the regional legislation have given the Pharmaceutical Industry an extraordinary competitive advantage in the USA. According to the Fortune Magazine (Fortune Magazine, 2001) the pharmaceutical industry was the most profitable industry in America in year 2001. Fortune Magazine also states that the 10 biggest USA pharmaceutical companies saw their gross profits increase by 33% in 2001 in spite of the American economic slowdown. From the literature review, it can be concluded that pharmaceutical lobbying has been extremely effective during the last years in the USA. It is cited by Holmer (2002), CEO of PhRMA with its “and zero defeats in the United States Congress”, and also by the interest groups of consumers as Congress Watch (2002), “they largely gets what it wants from politicians in Washington”. So that Pharmaceutical lobbying is extremely important for the Pharmaceutical Industry to maintain its competitive advantage. In the literature, there are some figures of how much it will cost consumers a certain tax break or the extension of a patent life but there is no research done analysing how much of the lobbying performed by PhRMA or by Pharmaceutical companies correlates to Companies Sales, Profits or Market Share except for special cases as the patent extension of Claritin, where an amount of 5.3 billion was estimated as the expected burden to consumers on the enacting of the extension of the patent life in 3 years (Manning et al, 2001). There is also no clear evidence in the literature that those companies that have in-house lobbyists have a better performance than those which do not have an in-house lobbyists. So that there is a benefit for the Pharmaceutical Companies which is the

equivalent of the damage to consumers but there is no study published on the impact of Pharmaceutical Lobbying in a microeconomics scale related to the performance of each company.

There is also the consideration of Suranovic (2001) about the nature of lobbying and its distributive characteristic, transferring resources from consumers or from the Government, in the case of tax breaks, to the Pharmaceutical Industry. There is a cost of opportunity so that those resources could be used for another needs of the patients or society. This issue is what the consumers groups or interest groups protest about. It can be concluded that consumers are being punished to the benefit of the Pharmaceutical Industry although the latter claims that it need these resources to research new molecules. The Pharmaceutical Industry claims that research is risky and that they need high profits to fuel new research. But there is evidence which shows that the pharmaceutical industry has been the most profitable for the last decades (Public Citizen's Congress Watch, 2002), so that the research could not be too risky otherwise it would not be that profitable. According to the Fortune Magazine(2001) the 500 pharmaceutical companies devoted 12.5% of their revenue to R&D compared to 18.5% to profits and 30.4% to marketing and administration. Even then there is one key player missing in the analysis, that are the Health Management Organisations or Managed Care Organisations who actually pay for a part of those medicines. There is also a distributive effect that transfers resources of these organisations to the Pharmaceutical Industry. Those extra resources could be used in improving the quality of Health Care or giving additional services to their affiliates.

Only in the case of the USA the improvement of the economic environment for the Pharmaceutical Companies, achieved through the lobbying in Washington, have created additional value. Redwood (2002) argues that as industrial policy on pharmaceuticals has been progressively abandoned in the European Union, the focus of pharmaceuticals and biotech investment has shift towards the USA away from Europe. " The most visible symptom of this is the gradual emigration of new investment in activities and qualities that determine industrial competitiveness in the long run: research, development, advanced skills and an entrepreneurial approach to new ideas". There have been many developments

in this direction in the past years: Pharmacia moved its corporate headquarters from the UK to the USA; Bayer moved its headquarters of its consumer medicines from Leverkusen to New Jersey; GSK after the merger moved its headquarters in the USA; Schering AG moved the management of its therapeutic division from Germany to New Jersey and Novartis is transferring its world-wide discovery and research activities to the USA (Redwood, 2002). What is noticeable is that these moves come from countries which are supposed to have the best economic climate in Europe as the UK, Germany and Switzerland. In this case, although lobbying had a distributive effect normally, it had a certain creation of value for the American economy as it improved the economic environment attracting industrial investments of foreign companies.

The nature of Managed Care

Pilnick, Dingwall and Starkey (2001) described Managed Care as a generic term for a variety of attempts to alter or restrict the treatment behaviours of health care professionals in order to produce both clinically effective and cost effective outcomes; at its simplest, Managed Care is the management of medicines and treatment aimed at containing costs and promoting effectiveness. Bengoa (1998) refers Managed Care as a net of organisations which provide co-ordinated health services to a certain population accepting the responsibility of the clinical and economic outcomes of the health in this population. Although Bengoa, cites this definition as Managed Care, he means a HMO, which is an organisation or group of them that contracts and supplies medical care on the basis of a fixed periodic payment.

Traditionally, physicians in the USA were paid a fee per item of service; this created incentives for overtreatment and cost inflation and presented payers with an open-ended financial commitment (Pilnick et al., 2001). Managed Care Organizations (MCOs), the majority of which in the USA are either health maintenance organisations (HMOs) or preferred provider organisations (PPOs), change these incentives, “eliminating fee for service in favor of delivery systems that encourage providers to control the costs” (Varney, 1995) limiting the financial commitment of payers by paying clinicians a periodic fee for life covered (capitation) and making them share the risks of costs for excessive or

expensive treatment. MCO payers may be employers, insurers, the state, or, more rarely, individual clients.

In practice, MCO organisational models vary considerably in detail and fee-for service providers have also adopted some features, such as the use of restricted drug formularies, blurring the distinction between the various types (Pilnick et al, 2001). A formulary is a list of FDA-approved drug products by therapeutic category, along with relative cost information; these formularies are made available to pharmacies, physicians, third-party payers, or other persons involved in the health care industry, to guide in the prescribing and dispensing of pharmaceuticals. A restricted or closed formulary limits reimbursement to the specific drugs listed (Varney, 1995). Pilnick, Dingwall & Starkey pointed out “However, the MCOs’ economic incentives are usually reinforced by a range of direct interventions. These typically include controls on clinical autonomy, controls on patient choice and a degree of vertical integration. Controls on clinical autonomy include restricting the physicians’ choice of drugs to those included in a formulary or requiring disease treatment to follow specified protocols. Those controls are intended to change doctor’s prescribing behaviour in line with measures of efficacy and cost efficiency. They may be enforced either by individual case reviews or profiling, where doctors’ performance indicators are compared with a standard and deviations from it are investigated or sanctioned.” The principal objective of formularies is to bring down costs selecting a narrower choice of drugs and adopting generics to replace the highly-price brand-name products. Motheral (2000) concludes that formularies can significantly reduce pharmaceutical utilisation in a non-continuously eligible population. But this diminishing of costs is controversial as Redwood (1997) describes: “Cost containment pure-and-simple can be counter productive, as large-scale pioneering study of integrated health costs and outcomes has recently demonstrated. After analysing 240.000 prescriptions and 99.000 office visits by nearly 13.000 patients in six health maintenance organisations across the US for one year, the study concluded that the most restrictive formularies had consistently caused the highest overall medical costs to HMOs and also caused patients greater inconvenience and longer periods of illness and discomfort”. Redwood makes a point about the effectiveness of Managed Care Organisations as the focus is only put in cost-containment of medicines and

not in outcomes an overall costs, specially, remark Studin (2002), in those diseases as diabetes, congestive heart failure, asthma and depression where the system have pronounced deficiencies. But Studin (2002) notices that the failure lay not in the formularies but in the imperfections of the whole system of Managed Care as lack of staff or capital in the MCOs to systematically adopt the practices of disease management or clinical-quality improvement, insufficient training of staff in such important areas as disease management, data analysis, and patient and provider education and the poor relationship with the physicians which undermines the health plan credibility. MCOs could also benefit from collaborative activities with the Pharmaceutical Industry in order to measure the effectiveness of the disease management programs.

Pilnick et al, (2001) describes as another characteristic of Managed Care the restrictions on the providers who may be consulted, whether for primary or secondary care, to those employed by, or holding contracts with, the MCO in question. As a result of such restriction and standardisation, whereby patients relinquish some freedom of choice, MCOs can offer care more cheaply than traditional fee-for-service schemes.

The evolution of Managed Care practices looking for cost containment paved the way for the surge of a new entity appeared called Pharmacy Benefit Management (PBM). According to Varney (1995), PBMs select participating pharmacists, drug manufacturers and suppliers, administer point of sale claims processing systems, negotiate quantity discounts with pharmaceutical companies, administer plan record keeping and payment systems, and maintain quality control. PBMs also control costs by negotiating discounts from manufactures, usually in the form of rebates, in return for placing the manufacturer drug on the PBM formulary. So that PBM are intermediaries between the Pharmaceutical Industry, the MCOs and the Pharmacies. PBMs are contracted by MCOs to handle their prescriptions and formularies. PBMs process the information of prescriptions from their selected pharmacies and generate information for the:

- Pharmaceutical Company: In return for the consumption done, the Pharmaceutical Company pays the PBM a rebate related to its Market Share.

- Managed Care Organizations: The PBM designs the formulary and provides the information to the MCO's in return for a fee that could be fixed on a capitation or per-service basis. Controls can be implemented on protocols and adherence to the formulary.
- Pharmacies: PBMs pay to the pharmacies the amount equivalent to the reimbursements done to patients.

The influence of the Pharmaceutical Industry in Managed Care Organisations

As there was no description of the activities of in-house lobbyists because of obvious reasons as they are chosen on one to one basis, there are some descriptions of the activities that a Managed Care Account Manager of the Pharmaceutical Industry should perform regarding the relationship to the Managed Care Organisations.

Managed Care Accounts Managers

The sources of this information are organisations which provided training for the Pharmaceutical Industry. Romar Consulting Associates (2002) refer to the Managed Care Account Managers to be responsible for building and maintaining strong positions for their companies in the Managed Care Organisations. For ASI Solutions (2002), another consulting company, the role of the Managed Care Manager revolves around developing and managing contracts with managed care organisations. Romar additions another activities as conducting an account portfolio analysis, establish objectives, strategies and tactics and work with the Headquarters personnel to support strategic account plans. These definitions are vague and none of them permits to clarify which is the job description but it confirms the existence of Pharmaceutical Managed Care Account Managers who worked with the Managed Care Organisations. Studin (2002) explains that Manager Account Executives are hired to foster long-term relationships with manage care payers as Pharmaceutical companies realised that the sales function could no longer just focus on physicians and hospitals but that Selling had an institutional requirement on non-physician decision makers. Pharmaceutical Managed care divisions are driven by their own contracting function, centred on the need to secure formulary positions. Collateral activities involve product pull-through. Standards for determining how Pharmaceutical manage care divisions perform revert to product sales.

Pharmaceutical Industry and the introduction of products in formularies

“Health plans (HMOs and PPOs) as a general rule distrust pharma, due to a perceived conflict of interest: financial support implies formulary positions are being sold, while partnerships compromise objective pharmacy and therapeutic (P&T) committee deliberations” (Studin, 2002). There is certainly an influence in the inclusion of products in formularies although denied by the HMOs/MCOs of the Managed Care Account Executives as some HMOs have prohibited medical and pharmacy directors from having meetings with Pharmaceutical Account Executives. Other National HMOs have prohibited program or grant participation or another type of hospitality with Pharmaceutical Companies and there are some HMOs which state that all the dialogue with Pharmaceutical companies has to be in a corporate level. A conflict of interest arise as the objectives of Managed Care Organisations are opposite to the ones of the Managed Care Teams of the Pharmaceutical Industry. The Pharmaceutical company’s objective is to maximise Sales in a formulary and the HMO or PPO is to contain costs and provide a better service to their affiliates. But the true influence of Pharmaceutical Companies is at the PBM level, where most formularies are done. In some exceptional cases the HMO contract a PBM preserving the right to decide which products are eligible for their formulary (Carroll, 2002) but most of the times the PBM decides about the Formulary and the products included.

In the USA, three PBMs, AdvancePCS, Medco Health Solutions, and Express Scripts covered 180 million people (Carroll, 2002) facts that shows a big concentration. Medco is owned by Merck Sharp & Dohme and it has one third of the PBM Market, a market estimated to cover 71% of the volume of outpatient medications covered by third-party payers (Lenzer, 2001). Eli Lilly also bought PCS Health Services, the biggest PBM in the country. The Federal Trade Commission (Varney, 1995) issued a consent decree regarding the PCS acquisition as it would harm competition in the national full-service PBM Market. The justification of the decree was that the purchase would create entry barriers for another pharmaceutical company. Lilly was obliged to create an independent Pharmacy and Therapeutics Committee aimed at deciding which products should be included in the Formulary. Lilly was also compelled to maintain a firewall between the two business with respect to other drug manufacturers’ proposals, bids, contracts, discounts, etc. Eli Lilly

divested its PBM after the consent decree. Merck Sharp & Dohme agreed to a similar consent with the Federal Trade Commission (Lenzer, 2001). Critics claimed that Merck's compliance with the consent decree is not perfect as it has its core products in the Formulary of Medco (Lenzer, 2001). Vioxx, its non-steroid antiinflammatory which entered the market in mid-1999 is in the formulary. Although the clinical studies prove that its selectivity over the COX-2 (cyclooxygenase-2) prevents the gastrointestinal side effects attributed to these type of drugs, new evidence shows that it produces an increase in cardiovascular events. Public Citizen's Sasich remarks: " Vioxx is no more effective- and it is no safer overall and its cost is significantly greater. So who does that benefit?" (Lenzer, 2001). This vertical integration is an effective way to secure the position in the formularies (Fons, 2002), but there is another way in which the pharmaceutical industry influence the design of formularies at the PBM level and the instrument are the rebates.

Carroll (2002) describes two typical types of rebate offered to PBMs: an access rebate that gets a drug on the formulary and a market-share rebate. Most access rebates are standard but the special deals between pharmaceutical companies and the PBMs is market share rebates, as an advantage in a therapeutic category may lead to a bigger market share in that category resulting in an improve in the bottom line and in stock prices.

Carroll explains that as PBMs are forced to cut pricing for handling prescriptions in order to compete for customers (HMOs, PPOs), they have implemented aggressive deals with Pharmaceutical Companies over rebates and discounts, being requested in return by the Pharmaceutical Companies to push more expensive branded medications. The Henry J. Kaiser Family Foundation conducted a study in year 2000 which concluded that saving through PBMs cannot be automatically ensured.(Lenzer, 2001). Clients of the Merck-Medco PBM saw their prescription drug costs climb from \$ 18 billion in 1999 to \$ 23 billion in 2000. As some of this formularies are tied to a consumption rate, the PBMs maintained their profits as the rebates and discounts have been kept secret by the PBMs (Carroll, 2002). Halbert, CEO of Advance PCS refers that the bulk of the rebates and discounts get passed on to clients but the clients cannot access to this information. The rebates help to keep the cost low for MCOs as helps the maximum utilisation of the drugs

of the formulary. There is also a secrecy on the different agreements of the PBM with pharmaceutical companies; it is common that representatives of the PBM urge physicians to use certain drugs, including branded medications. These agreements are paid separately under the terms of administrative fees or educational fees.

Critics claim that the big money of the Pharmaceutical Companies is tied to the most expensive medications on the market (Carroll, 2002) and that PBMs push higher-priced branded medications. Pharmaceutical Companies also use a tactic called “bundling” which means that the Pharmaceutical Company conditions its participation in the negotiation table with PBMs to the introduction in the formularies of its high-priced name brands. Needing the PBM to complete its formulary with some of the products of this company and its rebates, the PBM concede to introduce the requested products of this company. Bundling is also used for blocking competitors to be introduced in the formulary. Duramed Pharmaceuticals (Carroll, 2002) sued Wyeth accusing it to use bundling methods to block Duramed from a dozen different formularies. So that the inclusion of products in formularies is a controversial issue in the Managed Care setting. Although there should be an independent Pharmacy and Therapeutics committee to decide which products are included in a formulary and there are checks that none of the decision makers “inappropriately curry favour”(Studin, 2002) with the Pharmaceutical Companies, the reality is that Managed Care Account Executives exert influence in the inclusion decisions on HMOs or PBMs through rebates, special agreements or another means as Hospitality, Grants or Programs with key decision makers.

Summary

Pharmacopolitics in Argentina has been defined as the activities performed by the Pharmaceutical Industry aimed at influencing the Government, Public Officials and Health Management Organisations (HMOs) or Managed Care Organisations (MCOs) in order to get a competitive advantage in the Market. Pharmacopolitics main activities are, first of all, lobbying the Congress and the Government in order to get favourable legislation and second, influence the Managed Care Organisations to secure a position in the Formularies

of these organisations. Due to the lack of literature in Argentine Market, the American one was taken as a model as it has similarities to the Argentine Market.

Pharmaceutical Lobbying has been extremely effective in Congress devoting a huge quantity of resources to push through the legislation it coveted. This lobbying has been performed by the companies themselves or by PhRMA, the chamber which represents the Brand-Name companies. The Pharmaceutical Industry's strategy focus on three issues: protect themselves against competitors through extension of patents, preserve the price freedom and obtain advantageous tax breaks. The achievements derived from this focus protected the bottom line of the Pharmaceutical Companies making this industry the most profitable for the last decade. The opposition to this lobbying implemented by consumer's Groups or by a minority of legislators, did not prosper as the Pharmaceutical Industry worked as a Corporate body against them. Apart from the disparities in the level of lobbying investment, the fragmentation of the opposing groups, could not damage the initiatives taken by the industry united by the same objectives. Another issue of interest is the distributive effect of lobbying and how this distributive effect applies to the Pharmaceutical lobbying. Lobbying by nature is distributive as it does not create value as it only transfers value from one part of society to the other one. In the case of the successes achieved by the Pharmaceutical Companies, funds from consumers, HMOs/MCOs and the Government are transferred to the Pharmaceutical Industry. The Pharmaceutical Industry argues that it needs this resources to fund its research, research itself that will save lives in the future. There is controversy of the profits of the industry are not too high but there is no political will to change this fact. There is one peculiarity to be mentioned about the changes that the Pharmaceutical Lobbying create in the USA improving the economic environment. This fact attracted European companies to establish their headquarters and research facilities in the USA, creating lobbying, indirectly, value for the USA as new investments settled in the country.

Managed Care is described as a generic term for a variety of attempts to alter or restrict the treatment behaviours of health care professionals in order to produce both clinically effective and cost effective outcomes; at its simplest, Managed Care is the management of

medicines and treatment aimed at containing costs and promoting effectiveness. One of the components of Managed Care is the design of closed formularies which limits reimbursement to the specific drugs or products listed in the formulary. The aim of these formularies is to reduce pharmaceutical utilisation and thus costs. There is controversy about such an approach to medical care, not taking into account the outcomes of the use of medicines, which might reduce overall costs (hospitalisations, calls at physicians) for the Managed Care Organisations. For the time being, Managed Care Organisations are not prepared to introduce changes to the current policies towards medical practices and formularies. Usually the MCO signs a contract with a PBM (Pharmacy Benefit Management) who designs its formulary and process the prescriptions dispensed at the pharmacies. PBMs also negotiate discounts and rebates with the Pharmaceutical Industry in return for inclusion of certain products in the formulary. The tactics implemented by the Pharmaceutical Industry with the PBMs are vertical integration, buying a PBM and securing its products in the formulary; or agreements on rebates. The need of diminishing costs by PBMs make them lose their neutrality and they closed agreements with Pharmaceutical Companies on high discounts and rebates, in return for having the companies' high-priced products in the formularies. The effects of this policy is that formularies are not only based in the most effective and cost-effective products, but on the Marketing interests of the Pharmaceutical Industry.

The Pharmaceutical Industry has proved to be very effective in achieving its goals in the Congress and the Government or in the Managed Care Organisations. This effectiveness derives from the belief that Pharmacopolitics activities are essential for the development of the business, devoting an important amount of resources to obtain its objectives. PhRMA executes the Global Strategy of lobbying and advocacy groups pursuing the common interests of the whole industry. Each Pharmaceutical Company devotes additional resources to seek its own interests, building in-house structures aimed at lobbying the Congress or influencing Managed Care Organisations. Although no research has been published about the economic impact of Pharmacopolitics' activities in the performance of each company, evidence shows that these activities do have an important effect on business, improving the profits and the competitive advantage of the brand-name pharmaceutical companies.

References

- "rent seeking" The Concise Oxford Dictionary of Politics. Ed. Iain McLean. Oxford University Press, 1996. Oxford Reference Online.5
- "Interest Groups" The Concise Oxford Dictionary of Politics. Ed. Iain Mc. Lean. Oxford University Press, 1996. Oxford Refence Online.4
- "lobbying" A Dictionary of Economics. Ed. John Black, Oxford University Press, 1997. Oxford Reference Online.....5
- "lobbying" The Oxford Guide to the United States Government. JJ Patrick, RM Pious, DA Ritchie. Oxford University Press, 2001. Oxford Reference Online.5
- "lobbyists" The Concise Oxford Dictionary of Politics. Ed. Iain McLean. Oxford University Press, 1996. Oxford Reference Online.4
- A Pilnick, R Dingwall and K Starkey, Disease Management: definitions, difficulties and future directions. Bulletin of the WHO, 2001, 79: 755-763..... 16, 17, 18
- ASI Solutions (2002), <www.asi-solutions.com> 19
- B Motheral, TA Delate, JW Shaw and R. Henderson, The effect of a closed formulary in the face of real-life enrollment and disenrollment patterns. J Managed Care Pharmacy 6 (4): 293-297, 2000. Academy of Managed Care Pharmacy 17
- B Young, M Surrusco, The other Drug War: Big Pharma's 625 Washington Lobbyists. Public Citizen Congress Watch Publications, July 2001..... 7, 8, 9, 12
- C Wexler, D Steiner, M Shaffer and S Rabin, Prescription For Power: How Brand Name Drug Companies prevailed over consumers in Washington. Common Cause Publications, July 2001.....passim
- CA Varney, The dangers of Health Industry Consolidation and Corporization and the Effect on Quality, Cost and Access. Drug Industry Panel, Federal Trade Commission, May 1995 16, 17, 18, 20
- Cerasale V. (2000), Farmacoeconomía Aplicada. Revista Médicos, Argentina.....2
- F Clemente, A Greener, B Peck, A Benore, B Young and M Surrusco, America's Other Drug Problem: A Briefing Book on the Rx Drug Debate. Public Citizen's Congress Watch Publications, July 2002.....passim
- Fortune Magazine, Top Performing Industries, (2001) 14, 15
- Holmer AF (2002), In the Company of Heroes, PhRMA Meeting, March 2002
<<http://phrma.org/whoweare/annualmeetings/22.03.2002.501.cfm>> 5, 6, 10, 14

| | |
|--|----------------|
| I Studin, Reframing the Pharmaceutical Manufacturer/ Health Plan Relationship in Managed Care. Managed Care, February 2002 | 18, 19, 20, 22 |
| J Carroll, When success sours: PBMs under scrutiny. Managed Care, September 2002 | 20, 21, 22 |
| J Lenzer, The benefit of the Bargain: Link between drug company promo and formularies. Praxis Post, June 2001..... | 20, 21 |
| J Manning and J Fauber, Drug Makers depend on lobbying to protect patents. Journal Sentinel Online < http://www.jsonline.com:80/news/state/apr01/scripsid02020101a.asp > | 11, 12, 14 |
| JFons, Comentarios Iniciales. Demanda y Acceso a los Medicamentos, C Vasallo and MB Sellanes, Observatorio de Salud, 2002 | 21 |
| Jobst A (2002), Foreign Lobbying in the U.S.- A Latin American perspective. JEL, September 2002 | 3 |
| Lord MD (2000), Constituency-based Lobbying as Corporate Political Strategy: Testing an Agency Theory Perspective. Business and Politics, Vol. 2, No. 3, 2000 | 3 |
| Merriam-Webster Dictionary on line (2002), lobby. Merriam-Webster < www.m-w.com/cgi-bin/dictionary >..... | 3 |
| National Institute for Health Care Management, " Prescription Drugs and Intellectual Property Protection", August 2000 | 11 |
| National Institute for Health Care Management, Prescription Drug Expenditures in 2001: Another year of escalating costs, April 2002..... | 12 |
| Oxford English Dictionary Online (2002), lobby v., Second Edition 1989, Oxford University Press 2002 | 3 |
| Public Citizen's (2001), < www.citizen.org/30 years >..... | 7 |
| Quiñones V. Interview on Prospective View of the Argentine Health System, February 2002 | 2 |
| R Bengoa, Recent Tendencies and reforms of the Health Systems. Internal markets with and without competition and integrated health systems. Anales de la Universidad de Navarra, february 1998..... | 16 |
| Redwood H (1997), Pharmacopolitics 2000: cost containment vs. quality. Scrip Magazine February 1997..... | 2, 17 |
| Redwood H (2002), Whatever happened to industrial policy?. Scrip Magazine October 2002 | 2, 15, 16 |

| | |
|---|----------|
| Romar Consulting Associates, (2002)< www.romarconsulting.com/images/cdbrochure.pdf > | 19 |
| Suranovic S (2001), The Nature of Lobbying. International Trade Theory and Policy Lecture Notes, 2001. < http://internationalecon.com/v1.0/ch105/105c020.html > | 4, 5, 15 |
| Tobar F (2002), Volver a regular: el uso de la Farmaeconomía y los desafíos de la regulación de medicamentos. Publicaciones ISalud, Buenos Aires. | 2 |
| Vasallo C (2002), Interview on Prospective View of the Argentine Health System, March 2002 | 2 |
| Vasallo C, MB Sellanes (2002), Demanda y Acceso a los Medicamentos: El caso Antrax- Cipro como disparador del debate internacional. Observatorio de Salud, Medicamentos y Sociedad, Buenos Aires, 2002..... | 10 |

Methodology

Author: Javier de Renteria

December 2002

Methodology

Introduction

Federal legislation can have dramatic impacts on the strategy and performance of firms in the Health Industry. Being Health one of the most sensible issues for voters and for legislators, any law that is passed through the Parliament gets a lot of attention from the public. During the past few decades, legislators have had both economic and social motives for their increased commitment in health affairs. Legislators have selected specific areas of the Health Industry, or specific companies for monitoring standards, subsidies, protection, regulation or deregulation. The importance of the legislative process to health businesses has been highlighted by ongoing congressional debates over issues as medicines, HMOs and Medical Care.

In response to this active congressional agenda, corporations, as PAMI, Trade Unions HMOs, Professional Associations and the Pharmaceutical Industry have employed a wide variety of means to try to influence the legislative process. These influence tactics include financial contribution to the legislators or their parties, direct lobbying of legislators through professional lobbyists or direct lobbying of legislators by corporate executives. In recent years, corporations from the Pharmaceutical Industry have significantly increased their investments in the Corporate Executive lobbying. Departments have been created which not only devoted their attention to the lobbying with legislators but with all the key players in the Health System as HMOs, Government and Professional Associations. These type of activities done by the Pharmaceutical Industry in Argentina has been called by the name of "Pharmapolitics", as it has a clear relationship between Politics and the Pharmaceutical Industry.

Pharmapolitics activities essentially involve the motivation of key players in the Health System to introduce new politics and changes, which might be of interest to the Pharmaceutical Corporations. Some people suggested that Pharmapolitics activities are a highly effective mean, perhaps the single most effective mean, by which corporations from the Pharmaceutical Industry may influence the federal legislative process and the HMOs in the Health Industry. Despite the apparent significance, growth, and efficacy of

Pharmapolitics activities, there has been only limited research into this important phenomenon. As a result, Managers have only an ambiguous understanding of how, why or under what conditions Pharmapolitics activities might be more appropriate and effective. Though there are many popular assumptions about the nature and extent of businesses political power, there are no researchers who could predict the influence of Pharmapolitics activities in the legislative process or in the regulation of the HMOs and its consequences in the overall business of the Pharmaceutical Industry.

It will be first discussed how Pharmapolitics activities are incorporated in the companies and then it will be discussed the influence in business.

Pharmapolitics in the Pharmaceutical Industry

Corporate executives have been doing themselves the activities of lobbying with the HMOs and legislators until the 1990s. At that time there were some important changes in the regulations in the Health System. The first one was the PMO (Compulsory Medical Care) law, which passed through Parliament with little influence from the Pharmaceutical Industry. The second one was the introduction of Vademecums (Formularies in the USA) by the HMOs, looking for cost containment as Quiñones (2002) referred. Corporate Executives realised that they should change their approach and they devoted new resources for the objective of lobbying the HMOs and Legislators. They did not have enough time to keep pace with the new activities. For that purpose they created the Department of Pharmapolitics. Multinational companies appointed Managers who could be in touch with the people who made the key decisions, being them legislators, Managers of the HMOs or head of the Professional Associations. The objective of this Managers was try to influence the legislators or HMOs in their decisions to get some kind of competitive advantage for their companies.

This introduction could be regarded as been too late as it was a reaction to laws or decisions, which were prejudicial for the company as their products, were left out of the PMO or a Vademecum. These Managers were hired within the organisation, from departments as Sales or Regulatory Affairs. This was done to assure confidentiality and identification to the company. American Companies adopted rapidly this new concept of

Pharmapolitics as in the USA they have a similar function, which is called Managed Care Account Managers. The difference between the Pharmapolitics Manager in Argentina and the Managed Care Account Manager in the USA is that in the USA, the lobbying with the legislators is done by an in-house lobbyist or by separate body, which hire professional lobbyists (Public Citizenship (2001). Regarding the article of the Public Citizen (2001) there were 625 lobbyists of the Pharmaceutical Industry in Washington and \$ 92.3 Million dollars was the bill of this team of lobbyists for year 2000. In the last 8 years, according to Quiñones (2002), a new Position or Department has been created in the Multinational companies in Argentina named as Pharmapolitics Manager, Pharmapolitics Advisor, PR Manager, etc. As soon as the bigger Multinational Companies had a Pharmapolitics Manager, there has been as a domino effect and the others followed this trend.

The main objective of this position is to lobby legislators and the key people in the HMOs. The original main activity was to introduce the products of a company in the PMO or Vademecums during the 1990s, but currently the Position includes other responsibilities and activities. Still introducing the products in Vademecums is very important and consumes great part of the time of Pharmapolitics Manager.

The job description of the position is still vague in the companies but the job responsibilities are the following:

- 1) Introduce the products of the Company in Vademecums of the HMOs and maintain the products in them. Normally Vademecums are up-dated every year or every two years. They do not endure the same over the time as products are changed, new ones are introduced and another ones are taken out. For example, it could happen that a new product of a company is introduced and two other important products are taken out. So that the activity of maintaining the products is as important as that of introducing new products.

How is a product introduced in a Vademecum?

- a) Introduction Fee: There are HMOs, which have an introduction Fee that is an amount of money for a group of products. The Pharmapolitics Manager should decide which

ones according to the Marketing priorities. There might be some constraints regarding prices of the products. An example could be Amlodipine from Pfizer. Its price is double than that from the competitors with the same drug so that even if Pfizer pays for the introduction fee, this specific product might not be accepted.

- b) Price and pharmaeconomics analysis: The Manager of the HMO together with the Medical Controller decide which products will be introduced. Price and efficacy will be regarded as important issues to make the list of products. A Pharmaeconomics analysis must be presented by the Pharmapolitics Manager to persuade the Evaluation committee of the HMO that the product should be introduced.
- c) Rebate to the HMO: Some HMOs make a Vademecum with a group of companies, which have products that covered all the Therapeutic Classes and fulfil the PMO requested by the Government. Those companies have a competitive advantage in the population of the HMO as they have fewer competitors. In return of this preferential position, the Pharmaceutical companies will pay back a percentage of their own sales to this HMO. This modality has been introduced in the USA and it has been called "rebate". This rebate amounts to 8% to 25% of total sales. A contract is signed between the two parties and all the products of a company are introduced. The Pharmapolitics Manager has to make the necessary contacts to be invited by the HMO to participate in this Vademecum.
- d) Wholesalers with a special agreement with the Province HMO or Private: There are some wholesalers, which have a close relationship with HMOs as they sell them the drugs for Cancer, Aids and for other catastrophic diseases. Through this close relationship, those wholesalers have the possibility of introducing some products in those Vademecums. What the wholesaler request from the Pharma Company is a discount in price. Those discounts range from 15% to 25% of gross price. The Pharmapolitics Manager has to identify those Wholesalers and conduct the negotiations to have their products introduced in the Vademecums.

2) Relationship with the Chamber and its Vademecums: Some Vademecums are managed by the Pharmaceutical Companies Chambers. Usually these Vademecums are open so

that all the products of all companies are introduced. The companies pay a rebate back to the HMOs according to the company's sales in that HMO. The information provided by the Chamber about the Sales in that HMO should be analysed by the Pharmapolitics Manager and transformed in Marketing Information for the Sales Representatives. The Pharmapolitics Manager lobbying is also useful in this cases to get a higher reimbursement rate for the products of the company.

- 3) Relationship with the central Government, National, Provincial, Trade unions and Private HMOs: The lobbying activities that enable the Company to have a direct relationship to those key people should be done by the Pharmapolitics Manager. In case a law or a decree is against the interests of the company, the Pharmapolitics Manager is the one who should do the necessary lobbying to change that situation.
- 4) Pharmacoeconomics and disease Management programs: Those activities are also within the scope of the Pharmapolitics Manager.
 - a) Pharmacoeconomics: The objective of Pharmacoeconomics is to develop models of treatment using different compounds but analysing Price, Efficacy, Adverse drug reactions, Posology, etc. to define which treatment is more cost-effective for the HMO. Those models are usually developed by the Pharmaceutical companies to demonstrate that their new compounds are more cost-effective than the older products, even if the price is higher. The Pharmapolitics Manager does the adaptation of these international models to the Argentine Market.
 - b) Disease Management Programs: Those programs are developed by HMOs with the cooperation of the Pharmaceutical Industry aimed at issuing protocols for the treatment of patients with Chronic Diseases as Diabetes, Asthma or Hypertension among others. These protocols are based in Evidence Based Medicine, that means that protocols have been used for long and proved as effective and reliable. These Disease Management programs are tied to a commercial agreement with a Pharmaceutical Company or a group of Pharmaceutical companies achieving economies of scale and a reduction in the total expense. Patients receive the medication at home or in certain pharmacies near to their

homes. All records of patients are introduced in a database and the HMO can monitor the compliance of the patient to the treatment. For the Pharmaceutical Company is also advantageous as they have a monopoly position for its products in this group of patients.

Usually the Departments of Pharmapolitics Managers of different companies have different size, responsibilities and scopes of action. There are companies like MSD or Novartis with have between 6 to 8 people in the Department and there are others like Roche which have only two and is bigger in terms of sales than Novartis and MSD; the size and activities depend on each company and the requirements of the Headquarters. It is thus important to define which activities are common to all companies so as to be able to make comparison between them.

Influence in the business

As we consider the scope of activities that Pharmapolitics Managers are supposed to do, we could imagine that they are important and that their influence in business should be significant for a company. As said before, there is a general belief that this position is important for the success of the business but no analysis has been done of its relation to Sales or Market Share.

For the purpose of analysis we should divide those activities in two types:

- a) Activities that enable the company to have a better competitive advantage.
- b) Activities that are directly related to sales/results.

a) Activities that enable the company to have a better competitive advantage:

1) The first one of them is the introduction in Vademecums. With the introduction of the Company's products in Vademecums, the company has a bigger Market related to other competitors. The Economics Studies Department of CAEME (2001), the Pharmaceuticals Chamber of Multinational Companies, has issued for the year 2001 some information about

POPULATION WITH HEALTH COVERAGE
(000'S)

| | TOTAL | % OVER TOTAL POPUL. |
|---------------------------------------|--------|---------------------|
| Unemployed ¹ | 5.862 | 15,8 % |
| Sub-employed and evaders ¹ | 8.414 | 22,7 % |
| Population without Health Coverage | 14.276 | 38,6 % |
| PAMI ² | 3.369 | 9,1 % |
| State Employees | 7.000 | 18,9 % |
| Private Insured | 4.202 | 11,3 % |
| Trade Unions HMOs ³ | 11.609 | 31,3 % |
| Population under Health Coverage | 26.179 | 70,7 % |
| Total Population ⁴ | 37.032 | 100,0 % |
| Population with Double Coverage | 3.423 | 9,2 % |

(1) INDEC, information Oct 2000: Unemployment rate (14,7%), sub-employment (14,6%) and evaders (6,5%).

(2) PAMI Agreement with the Chambers, Up-Date Information July 2000

(3) Superintendence of Public Services, "Obras Sociales. Información General del Sistema". Vol. 2 (1999).

(4) INDEC, Annual Statistics 1999. Proyección demográfica de la PEA y Población total para el año 2000.

the Market of HMO and its breakdown. The following chart shows that the people without Health coverage are 14.276.000 accounting for 38.6% of population. The other 22.756.000 is the people who have Health Coverage and can afford paying Medicines. There are 3.423.000 that have double coverage, which means that they belong to more than one HMO. The reason for that is that there are people who are in a Trade where they are obliged to be in a Trade Union HMO and they have a Private HMO additional to the Trade Union one.

The Market under Vademecums is that of the Trade Unions HMOs, the State Employees and PAMI. So that 81.9% of the people with Health Coverage are under a policy of Vademecums. There could be some HMOs within this Universe that have no Vademecums. The precise size of the Market will be discussed later in this paper but for the purpose of the discussion this information will be considered for the time being.

Why are Vademecums so important?

Patients get a discount in the Pharmacy for those products that are in the Vademecum of the HMO. For those products that are not included, patients get no discount. Discounts range from 40% to 100% in some products. Patients request physicians to prescribe those

products, which are in the Vademecum of their HMO. So that if the market is of 22,7 million people and 81,9% of them are under an HMO with a Vademecum, Pharmaceutical companies should have their products in the Vademecums. The Pharmapolitics Managers main activity is to achieve this objective.

2) The second important activity of the Pharmapolitics Manager is to try to influence legislators to issue regulations that improve the competitive advantage of their company or at least that it is not prejudicial for it. For example, we could quoted the PMO (Compulsory Medical Care) reform that stated products for the treatment of Diabetes should have 100% reimbursement. How was this law important for those companies in the Diabetes field? It increased the possibilities of getting patients, as the medicines should be paid by the HMOs. Was it a clear advantage for those companies? Certainly it was but the reform of the law did not say that all diabetes products should be included in the Vademecums. HMOs covered the cheapest and oldest products and excluded from the Vademecums the new ones. Those confirmation was done by M. D. Lord (2000) which says:....are more effective for influencing legislators decisions to support or oppose proposed legislation than for influencing the specific content of proposed legislation.

3) The third issue is the relation with the Chambers. A company, which is active in the Chamber, has a trend to get some advantages, for example, a higher reimbursement for the patient, when a commercial agreement or Vademecum is agreed with a HMO, for example PAMI.

b) Activities that are related to Sales/Results:

Pharmapolitics Managers are in charge of implementing Disease Management Programs. These programs give the Company a Monopoly or an Oligopoly over a certain Disease in an HMO. The products, which are commercialised, are those ones from one company or two or three companies. The Company's Sales to the population with a certain disease of that HMO will increase proportionately to the previous Market Share in that indication. For example, it will be considered Glaucoma (Hypertension in the Eye), disease in which AlconLabs (the leader in Ophthalmology products) owns a Market Share of 33% in that HMO. Alcon could replace 62% of the prescriptions for Glaucoma for this HMO except

for the prescriptions of Alfa-agonists (product that Alcon does not have), which account for only 5% of the Market Share in this HMO. So. An additional 62% to the 33% that it already has represents a 188% increase in Sales in that HMO. So that the activity of Disease Management Programs have a direct relationship to Sales.

Origins of the research

No research has been done in the subject of Pharmapolitics in the Multinational Pharmaceutical Companies in Argentina. The topic of research is to try to determine if this type of lobbying has an impact in terms of Sales or Market Share and try to understand if this lobbying has an effect in overall performance in these Companies. According to the Merriam Webster Dictionary, to lobby is: "to conduct activities aimed at influencing public officials and especially members of a legislative body on legislation", which corresponds to the activities of the Pharmapolitics Manager.

The reason for the research being conducted was that the answers for following questions were still not fully known by the Marketing Directors or General Managers of the Multinational companies in Argentina:

- 1) What is the job description of a Pharmapolitics Manager in the Multinational Companies?
- 2) How big is the market of HMOs with Vademecums in terms of patients and which was the development of it during the last years?
- 3) Are the Multinational Companies with a Pharmapolitics Manager more successful in terms of Sales/Market Share than those Multinational Companies without one?

So that the research has been undertaken to try to find an answer to these questions.

Aims of the Project

The aims of the project can be stated as:

- 1) To define a common spectrum of activities which could define the job description of the Pharmapolitics Manager Position in the Multinational Companies in Argentina.
- 2) To establish the size of the segment of the market with Vademecums and its development through the years.
- 3) To test whether the Multinational Pharmaceutical Companies with a Pharmapolitics Manager are more successful in terms of Sales and Market Share than those Multinational Companies without one. The objective is to find an x-factor, which shows the better performance of companies with a Pharmapolitics Manager.

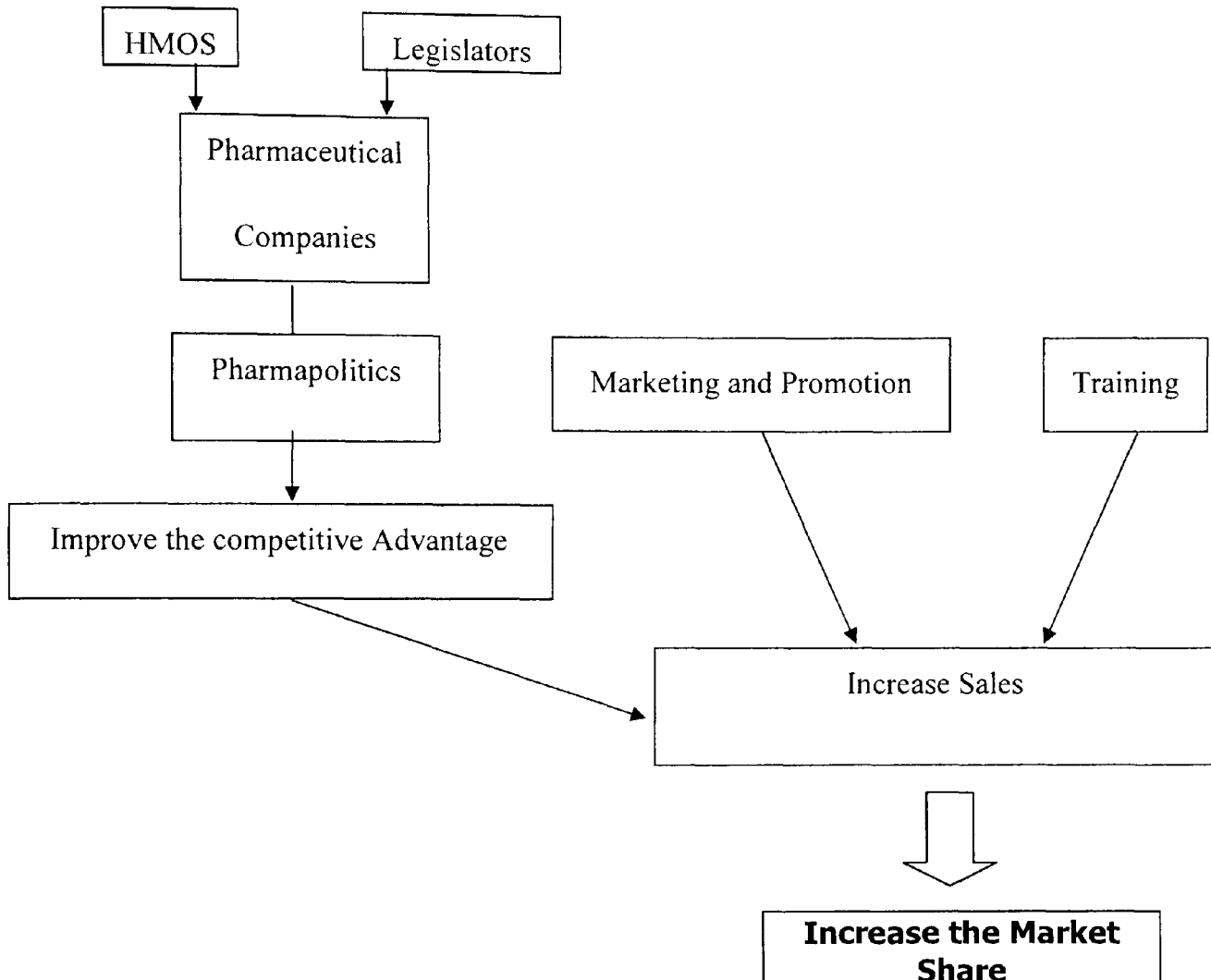
Content of the research universe

The research area will be the Multinational Companies from the Pharmaceutical Industry in Argentina, which account for 49,1% of the Ethical Pharmaceutical Market (IMS Oct'02). There are 45 Multinational Companies in Argentina in the Pharmaceutical Industry. 16 of them have created the position as Pharmapolitics Manager in the last 5 years. They account for 35,5% of the Ethical Market, (IMS Oct'02) . They are Novartis, Roche, Aventis, Wyeth, Alcon, Pfizer, Pharmacia, Bristol Myers, AstraZeneca, Altana Pharma (ex-Byk Gulden), Boehringer Ingelheim, MSD, Schering Plough, Janssen, Abbott and GSK. The rest have no Pharmapolitics manager.

The comparison will be between the Multinationals who have a Pharmapolitics Manager to the ones that do not. The period considered for the evaluation will be from 1997 to 2001, beginning January 1st., 1997 and ending on December 31st., 2001. Years 2002 and 2003 are not been considered in order to eliminate the outliers. There are considerations to do referring years 2002 and 2003. There has been a strong devaluation in Argentina (350%) during 2002 and prices of Pharmaceutical products have been increased in a lesser degree (75%). The issue is that the increase in prices has not been the same for all the companies so that taking this year could lead to distortion of the analysis. It could happen that through devaluation some companies have increased their prices in a lesser degree than the others and have a substantial difference in Sales or Market Share by the end of December 2002. For example, if we take two similar companies as Pharmacia and GSK selling 113 Million

and 108 Million pesos (IMS Oct'02) a year and a market share of 3.33% and 3.21 % respectively and GSK increases its prices by 30% and Pharmacia by 20% following the average increase in the Market, GSK will have an increase on Market Share of 0.25 due to the difference on the rate of price increases and not due to commercial performance. This difference could be temporary or definitive but in the actual scenario of economic uncertainty, taking into account the figures of year 2002 could mislead the research. So that for the methodology, 2001 will be taken as reference and the calculation of Sales and Market Share will be done in pesos as it appears in the information of IMS. The information will be regarded to sales accounted by IMS. IMS is an international company that audits the sales of Pharmaceutical Companies as Nielsen does for Consumer Companies. IMS reckons only Sales done in Pharmacies open to the general Public. Hospital Pharmacies, Trade Unions Pharmacies, On-line pharmacies and Community Hospitals Pharmacies are not considered. The price, which is considered by IMS, is the price that Wholesalers sell to Pharmacies, so that the 16% margin of the Pharmacies is not considered. These prices do not include the discounts made by Wholesalers to Pharmacies. Sales made to Hospitals or Government directly by the Pharmaceutical Companies or Wholesalers, are not included for the calculation. Sales of products for Catastrophic Diseases as Cancer, Aids, and Haemophilia are not included as they are bought directly from HMOs or the Government. The validity and reliability of information is high as IMS information have a coefficient of error of +/- 5%. The sample taken by IMS for making its projections derives from Sales done from Wholesalers to Pharmacies. This sample represents 65% of the Ethical Market. The Ethical Market is the Market of prescription drugs. It does not include Over-the-counter products. The units of research will be pesos as they appear on the IMS information. IMS convert the local currency (pesos) into dollars every month to make their calculations, but as during the period of analysis the dollar was pegged 1 to 1 to the peso, pesos will be considered. All Multinationals companies will be considered. All Sales considered are IMS sales.

The conceptual or theoretical Framework



The conceptual framework or theoretical framework is the following. There are HMOs and Legislators, which take decisions that affect Pharmaceutical Companies. Pharmaceutical Companies have created the position of Pharmapolitics Manager to lobby these people and influence their decisions in favour of the companies. The Pharmapolitics Manager has to provide their companies with two types of activities: those, which improve the competitive advantage of the company in the market or those who directly increase sales. Those two types of activities will produce in an increase of the Market Share of the company. On the other side Marketing and Promotion activities and Training of the Sales Representatives

also produce increase of Sales and Market Share in the companies. It is assumed that all companies in the Research have done Marketing and Promotion activities and Training of the Representatives in a similar degree through the five years of time considered in the Research so that the only difference will be having or not a Pharmapolitics Manager.

The research design

It is considered that the people who could better describe their activities were the Pharmapolitics Managers currently in the job. They know perfectly the activities that they are responsible for and can give precise information of their priorities. In the cases of Multinational Companies without Pharmapolitics Manager, the person in charge of doing these type of activities would be the Marketing Director or Sales Manager so that they would be chosen for the survey. For the purpose of confirming the assumption that all companies did Marketing, Promotion and Training Activities the Sales Manager or Marketing Director will be considered for the Survey as they have the information about these activities.

- 1) The first design consideration represented a collection of all the activities done by the Pharmapolitics Managers of the 16 companies with a Pharmapolitics Manager to establish which activities are common to all. The different job descriptions could provide a common pattern for all the companies, which will be used afterwards in the analysis.
- 2) The second design consideration represented a collection of all the Pharmapolitics activities done by the other 29 Multinational Companies without a Pharmapolitics Manager. The Sales Manager or Marketing Director will be surveyed to know which is the emphasis and differences within these companies and the ones with a Pharmapolitics Manager.
- 3) The third research consideration to follow is to measure, which is the size of the ethical market with HMO under Vademecums compared to the market of HMOs without Vademecums. In this consideration we will have to exclude the market of those people

without any kind of insurance, as their purchasing power is marginal. "They do not buy medicines or they are provided by the state" (Neri 2002).

- 4) The fourth research consideration is to confirm that the Multinational Companies have done Marketing, Promotion and Training in a similar degree through all the period. For this purpose two different resources will be considered. The first one will be the Marketing Directors or Sales Managers of all companies through a survey. On the other side, introduction of new products will serve as a double check as new introductions shows the use of resources for Marketing activities and Promotion. It is a reliable way to know the Marketing activity of a company. The information of new introductions will be taken from IMS.
- 5) The fifth research consideration will be whether those companies with a Pharmapolitics Manager have a better market performance that those that do not have any Pharmapolitics Manager. It should be noticed that only Multinationals are analysed because of their similarities in their business policies in the Market. National companies have not been taken into account as they do not have the same organigram as the Multinationals and the owners or General Managers often do the activities of Pharmapolitics. In some cases they are done in the level of the Sales Representatives or Sales Supervisors.

The inductive and deductive process of the researcher

The approach to the research will be mainly positivistic. Even if the first paper with the in-depth interviews done to the members of the Political Parties and from the Multinational Companies Chamber is phenomenological and judgemental, the whole approach to the research will be positivistic. The aim of the research is to get generalisability for the following topics: a job description for the position for Multinational Companies and a factor-x that will enable to take decisions regarding the appointment or not of a Pharmapolitics Manager for a General Manager of a Multinational Pharmaceutical Company in Argentina.

For the purpose of finding a general pattern for the job description of Pharmapolitics Manager a survey will be conducted to all Pharmapolitics Manager in this segment so as to find a clear picture of differences and similarities in their jobs. On the other side, to test the theory that Multinational companies with a Pharmapolitics Manager have a better performance than the other companies without one, the dependent variable will be Market Share and Sales and the independent variable will be the existence or not of a Pharmapolitics Manager Position or Department in the Company. The results will be statistically controlled in the study. For the purpose of defining the degree of Marketing, Promotion and Training activities, a positivistic approach was taken with a survey to the whole universe that means all the Multinationals companies. To double-check that information, products launches will be taken from IMS and compare the validity of the Survey.

The only issue that the researcher is confronted with is the lack of reliable information is the size of the market under Vademecums. The reliability of information is high in the last two years as there is the researcher has an archive with hard copies of all the Vademecums in the Market with the number of affiliates of each HMO. But from the period between 1997 to 2000, the researcher does not possess this information. One of the ideas considered, was to ask the Pharmapolitics Manager whether they think that the Market under Vademecums has been growing in the period between 1997 to 2000. But the answers will be biased and unreliable. The best alternative found was to get the authorisation of the Pharmapolitics Manager of Novartis to ask for information to the Statistics Manager for Pharmapolitics from Novartis, Miguel Mantecon. He has hard copy of all the Vademecums, including the number of affiliates since 1995. He also has a database of all HMOs and their evolution in time. The authorisation has been achieved and the evolution of the size of the Market could be precisely defined between 1997 and 2001. The only hindrance is that the researcher would not have the hard copy of all the material. Nevertheless the analysis of the size of the Market under Vademecums will be positivistic.

Hypotheses and Propositions

First: The activities of the Pharmapolitics Manager are not homogeneous but a common pattern can be found.

Different companies have different profiles and different responsibilities for their Pharmapolitics Managers. A broad description of the different activities was given before including lobbying to legislators, lobbying to HMOs aimed at introducing the products in Vademecums, implementing Disease Management Programs, lobbying in the Multinational Companies Chambers, negotiating with Wholesalers and Professional bodies, adaptation of models of pharmacoeconomics and implementing them. There are companies with a Pharmapolitics Department with more than one person and other companies, which have only a Pharmapolitics Manager. There are some companies, which give the Pharmapolitics Manager great freedom of action and others in which the Pharmapolitics Manager is constrained in what they can do. But although being not homogeneous there can be two types of job descriptions, which could be found: a narrow one which entitled the activities that all of them do and a broad one entitling which are the ideal activities that a Pharmapolitic Manager should perform. That will give us an idea of the do and ought.

Second: The companies without Pharmapolitics Manager tend to do fewer activities than those who do.

There are 29 multinational companies, which have no Pharmapolitics Manager at all. These activities are performed by the General Manager, Marketing Director, Sales Director or Sales Supervisors. They are not done in a regular basis but by request. The amount of time and effort given to these lobbying activities in the whole organisation is much lower than the ones who have a Pharmapolitics Manager. The objective is to describe which activities are done and how much resources are devoted within the organisation to dot these activities.

Third: The market of HMO with Vademecum has increased in the last 5 years.

Due to the crisis, the HMO looking to curb the costs have been going through a process of open prescription for their patients to a process of closed Vademecums for them. The costs

for the HMOs diminished as the physician has fewer variables to give to the patient. For example, in the case of osteoarthritis in a knee. The patient could receive an antiinflammatory (diclofenac), an antiinflammatory cream (capsaicin) and a nutrient for the cartilage (glucosamin). The cost of the monthly treatment will be: \$ 80.62 (Manual Farmaceutico Dec'02) for Voltaren (Diclofenac), \$ 40,36 (Manual Farmaceutico Dec'02) for the cream Redol Forte (Capsaicin) and \$ 143.47 (Manual Farmaceutico Dec'02) for the nutrient Adaxil (Glucosamin). As in the Vademecum there is only Voltaren tabs and a cheaper cream with Diclofenac, the patient receives Voltaren \$ 80,62 and Dioxaflex \$ 20,78 (Manual Farmaceutico Dec'02). It sums \$ 101.40, which the HMO pays the half of it: \$ 50.7. In case there is no Vademecum the patient would have received all of them summing up \$ 264.45 paying the HMO \$ 132.23. In this case there is a 161% difference. The narrowing of the choices derived in a lesser use of the medicines and a lower cost for the HMO. It should be said that HMOs also introduce in the Vademecums Generic Products with a lower price in order to diminish the costs. Motheral (2000) concluded: "Formularies can significantly reduce pharmaceutical utilization in a noncontinuously eligible population."

Fourth: Those Multinational Companies with Pharmapolitics Managers have a better performance than those Multinational Companies with no Pharmapolitics Managers.

The company with a Pharmapolitics Manager tend to have a greater introduction of their products in Vademecums hence they tend to have a bigger market for promotion of their products. Even if two companies have the same performance in the same Therapeutic Class, the one with a bigger Market will have more absolute Sales. The lack of incorporation of the products in the Vademecums narrows the market for those companies without Pharmapolitics Managers. If the proposition three happens to be true, Companies whose products are not in Vademecums will compete in a smaller market. The market free of Vademecums will be only 18,1% of the whole market. The other activities done by the Pharmapolitics Manager improve also the competitive position of the companies in order to be more effective with the Marketing and Promotion.

Assumptions

The first assumption is that the Pharmapolitics Manager will do his job and that he will have no constraints in the activities of introducing products in the Vademecums or doing other type of activities.

The second assumption is that only Multinational Companies are considered and not National Companies in the sample as they have another methods to produce the Pharmapolitics effects.

The third assumption is that all Multinational Companies continue with their normal Marketing, Promotion and Training activities and that none of them has stop calling at physicians.

Methodology

Design and choice of instruments

Prior to the interviews with the Pharmapolitics Manager, interviews were done with some key people from the political parties and from the Pharmaceutical Industry. These in-depth interviews provided background information to aid in the design and administration of the survey instrument. It also gave background information about the Health System and how it might evolve. The history of the Argentine Health System is described by the politicians and it gives the introduction to the subject that it is going to be researched: Pharmapolitics. The methodology for this part of the research is phenomenological, inductive and the idea was to focus in a judgemental methodology where the participants because of their knowledge and experience could address the questions as representatives of a whole class, in this case representing the Radical Party, the Peronist Party and the Pharmaceutical Industry. The interviews were taped and the respondents were aware of the objective of the research. Regarding ethical considerations, oral consent was requested of using this information for the paper and a hard copy of the paper was sent to them by registered Post to their offices. All the information that is included in the paper derives from the interviews.

To achieve the common activities related to the Pharmapolitics Manager, all Pharmapolitics Managers (16) will be surveyed. The total universe was considered, as the sample is too small. Accessibility to these Managers is possible and the reliability of their answers would be high. A possibility considered was interviewing the superiors of the Pharmapolitics Manager also to see whether the opinions match or not. But accessibility to this group of people was not easy and this double check with the Pharmapolitics Manager might distort the validity of the answers of the Pharmapolitics Managers, so that the researcher opted for only interviewing the Pharmapolitics Managers. In depth-interviews could be done but the problem of this approach is that although the richness of the information, it could be difficult to find common patterns in the activities. So that a questionnaire will be done and the survey will be based in the questionnaire. The survey contained a variety of different measures. To generate a richer response set and to assure validity and reliability of all the measures used, survey participants will be asked to respond to a variety of multiple scaled items, ordinal ranking items, semi-structured questions and open-ended questions. The multiple scaled items used a ten-point response scale with zero indicating no influence and ten indicating the highest level or degree of importance. Pharmapolitics Managers will be asked about their own offices than rather in reference to a typical Pharmapolitics office. Confidentiality will be granted and the researcher will put special emphasis that no response would be construed as representing either the particular respondent or their specific company. That is used to eliminate respondents concerns about socially undesirable responses that might negatively reflect upon the respondents or their companies. The questionnaire is aimed at defining the job, defining the activities involved and how much resources is devote to them, relative importance of this activities in achieving a better performance of the company and relative and absolute measures of their work. One chapter will be devoted to register how much time is consumed by the different activities during a month. Another important question is the relative position of them in the hierarchy of the company and which line of report there is. All information will be tabulated and processed. The sample comprises the Universe and due to the size of the sample, the information will be presented according to the number of mentions and not in percentages.

On the other side the same questionnaire will be filled by the 29 Multinational Companies which do not have any Pharmapolitics Manager Position or Department. There will be personal interviews with the Marketing Manager/Director or Sales Manager who is in charge of the Pharmapolitics activities. The same considerations taken for the 16 Pharmapolitics Manager in terms of confidentiality will be taken for these Managers. The objective of having the same questionnaire for both groups is the possibility of making them comparable and arrive to conclusions from the information collected during the survey.

For the purpose of measuring the size of the Market under Vademecums and its evolution during the period 1997-2001, several possibilities were evaluated. The first one was to ask the Pharmapolitics Managers about their thoughts about the evolution of this Market. It was disregarded, as the information will be biased and not reliable. The other one was to try to find an archive with the information of the Vademecums during those years. The researcher has only the information of the last two years, 2001 and 2002. Historical information is not available in the HMOs so that only a Pharmaceutical Company could have a complete archive. The researcher found that Novartis has the information and all the Vademecums in Hard Copy with the number of affiliates. Authorisation was requested to the Pharmapolitics Manager of Novartis so as to have access to this source of information. Novartis gave its approval so that the size of the Market will be measured from the information of the Vademecums issued in the period 1997 to 2001.

For evaluating the performance of the companies, information from IMS in pesos will be considered. The annual figures from Sales and Market Share will be those of December for each year. The process will be quantitative and a direct relationship will be sought between performance in Multinational Companies and the inclusion of a Pharmapolitics Manager in the pay roll of those companies. For validating the assumption that all Multinational Companies will try to sell their products making their best effort and that they will have a similar degree of Marketing, Promotion and Training activities, a survey will be made among Marketing Directors or Sales Managers. Accessibility to this group of people could be difficult so that when an interview could not be done, another person down in the hierarchy will be sought to answer the questionnaire. To double check the information

received in the Questionnaire and proved its reliability, new introductions of products by these companies will be checked in the information provided by IMS. Launching of new products is a valid information to measure the degree of Marketing activities as there is a considerable use of resources invested in a Launching.

The source of data, their availability and access

The source of the data will be two:

- 1) Surveys: There will be three different groups for the surveys.
 - a) The first one will be the Pharmapolitics Managers of the 16 Multinational Companies with Pharmapolitics Managers or Department. The accessibility is easy and the information of the Questionnaire will be tabulated and processed in Excel or Access. The size of the sample, although being the whole universe, is too small to show any percentage of the conclusions. The number of mentions will be stated instead of percentage.
 - b) The second one will be the Marketing Director or Sales Managers of the Multinationals without Pharmapolitics Manager. Accessibility to this group of people could be more difficult. In case, there is no possibility of interviewing one of them, a representative person will be sought down in the hierarchy. The information will be processed and tabulated as in the first group. The same consideration applies regarding the size of the universe. As it is too small, the number of mentions will be stated instead of percentages.
 - c) The third group will be the same people as in group two for the companies without Pharmapolitics Manager. In this case, it will be convenient to do the survey together with the other one, as accessibility to this group of people is difficult. For the companies with Pharmapolitics Manager, the Marketing Director or Sales Manager will be interviewed. Information will be tabulated and processed. Even if this group is bigger, mentions instead of percentages will be considered. In case there is a company does not fulfil the criteria of similar

degree of Marketing, Promotion and Training activities, it will be withdraw for the final analysis of performance.

2) Information from IMS: There will be two different issues to be investigated: annual figures and introduction of new products by Multinational Companies.

a) Annual figures IMS: this information will be transferred directly from the database of IMS to assure its accuracy and it will not be taken from the books. The information will be taken in pesos (\$). The methodology to gather the information will be electronic through IMS and Sales in pesos will be taken every year by the end of December. Market Share will be taken also in pesos. No over-the-counter products will be taken into consideration, as they are not incorporated into Vademecums. The importance of knowing the demand figures and not the internal Sales of the companies is its validity and reliability; internal Sales have always distortions related to the achievement of the forecasts. IMS figures are an international standard regarding Pharmaceutical Products. The sample of IMS of the Market is the Wholesaler chains accounting for 65 % of the total Sales in the Ethical Market. IMS measure the sales from Wholesalers to Pharmacies and their accuracy is high. Validations of the data are done every 6 months. There are some limitations as referred before. Sales made to Hospitals or Government directly by the Pharmaceutical Companies or Wholesalers, are not included in the calculation. Sales of products for Catastrophic Diseases as Cancer, Aids, and Haemophilia are not included as they are bought directly from HMOs or the Government.

c) Introductions of New Products: In this case, monthly information of IMS will be considered to determine which products have been introduced by the Multinational Companies in the period 1997-2001. This information will be tabulated and a table with the different companies will be done.

The data collection process

- 1) Interviews with Pharmapolitics Managers: the whole Universe was chosen, as the sample is too small to proceed with any kind of sampling. The possibility of taking the entire Universe makes the information reliable and valid. The interviews will be done from March to June 2003. The interviews will be done in a neutral place, not in the office of the Pharmapolitics Manager so that there are no interruptions and the atmosphere is relaxed.
- 2) Interviews with Marketing Directors/Sales Managers: the whole universe of companies will be considered. The sample is too small to proceed with any kind of sampling. The information will be reliable and valid. Contrary to the Pharmapolitics Managers, the interviews will be conducted in the office of the Managers so that it will be easier to get an interview for the survey. These interviews will be done between April 2003 and October 2003.
- 3) Information from the Archive of Novartis: the information and the authorisation are now available. The collection of this information will be as soon as possible as political changes within the company, could make the access impossible. Therefore the information will be collected in February 2002 and it will be tabulated and processed. There is also some Vademecums in electronic format. Those Vademecums will be requested and kept in the researcher's file.
- 4) Information from IMS: IMS information has to be converted to an Excel or Access format. The processing is done by IMS. The information will be requested on March 2003. Authorisation has been obtained from Alconlabs to use this information for the Thesis. The request of the information will be done by Alconlabs to IMS.

Complementary data collection processes

Another complementary process is going to be done to check the Questionnaire. Two retired Pharmapolitics Managers and two retired Sales Managers will be interviewed to check the Questionnaire in order to test it before the real interviews take place. Corrections will be made upon suggestions of the respondents.

Analysing the data

- 1) The survey will be tabulated in two tables: Group 1 (Pharmapolitics Managers) will be compared to Group 2 (Marketing Directors/Sales Managers) regarding the frequency and importance of Pharmapolitics activities. The same questionnaire will be used so that figures will be comparable. Access will be used for the tabulation and the information will be displayed as Excel. Statistically significant information will be considered and outlined.
- 2) Survey of the Marketing, Promotion and Training Activities: The response of the different Managers will be tabulated and outliers will be analysed apart in order to confirm if there has been a different degree of activity to the other members of the group. In case there is a company with fewer activities than the others, it will be taken away for the analysis. This information will be consolidated with the information about new introductions in the Market from IMS.
- 3) IMS provides the information in the format Access. For the purpose of the analysis all information will be in pesos and it will be annual figures. The information will be the one of the Total Ethical Products for the company. No over-the-counter products will be included. Once the data is homogeneous, the statistical analysis tools of Excel will be used to find a correlation between the variables.

Ethical issues

Regarding the ethical issues of the data, permission was obtained from Alconlabs to use this information for the thesis. The information will be obtained from Alconlabs data- base in a format access. The researcher as an employee of Alcon has the right to use this information for research and for the Thesis. The permission of IMS to use the information will be valuable as the researcher can make this information public. The only authorization of Alconlabs is enough for the purposes of the thesis, but nevertheless the authorisation of IMS will be sought.

Regarding personal interviews a consent form will be asked to all the participants and it will be assured that neither information will be sent to the public or to their companies. Taped interviews will be avoided in the personal interviews, as the Managers are not accustomed to this practice.

Interviews to the politicians and members of the Multinational Companies Chamber were taped. An oral consent was asked and a copy of the Paper was sent to them by Registered Post.

References

- CAEME (2001) Quiñones V., Economic Studies Department of CAEME, Oral Presentation, April 2001.....7
- IMS October 2002, Main Laboratories in Argentina in Values Page 1 and 2, Ethical Market.....11
- Lord M.D. (2000), Constituency Lobbying as Corporate Political Strategy: Testing an Agency Theory Perspective, Business and Politics, Vol. 2 No. 3, 2000 Carfax Publishing.9
- Manual Farmaceutico, Editorial Alfa Beta December 2002.....18
- Motheral (2000), The effect of a Closed Formulary in the Face of Real-Life Enrollment and Disenrollment Patterns, J. Managed Care Pharmacy 6 (4): 293-297,2000. Academy of Managed Care Pharmacy.....18
- Neri A. (2002) Interview on Prospective View of the Argentine Health System, February 200215
- Quiñones V. Interview on Prospective View of the Argentine Health System, March 2002 3
- Young B and Surrusco M (2001). The Other Drug War: Big Pharma's 625 Washington Lobbyists. Public Citizen, Congress Watch, July 2001.....4